Quality Management Plan

U.S. EPA - Region 6

Revision 13 / QTRAK No. 20-408

October 2020

U.S. Environmental Protection Agency
Region 6
1201 Elm Street, Suite 500
Dallas, TX 75270-2162

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Quality Management Plan Identification Form

Document Title:

Quality Management Plan for EPA, Region 6

Document Control Number:

QTRAK number to be assigned upon Region 6 routing

Organization Title and Address:

EPA Region 6
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Regional Administrator:

Ken McQueen

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Plan Coverage:

The plan covers all of the monitoring and measurement activities mandated through EPA regulations and memoranda. This includes all internal and external environmental data generated by monitoring activities conducted through Regional program activities, contracts, grants, interagency agreements, and cooperative agreements. The Quality Management Plan primarily covers the activities of the Regional Quality Assurance Manager, Quality Assurance Staff and the Quality Assurance responsibilities of the Divisions, Offices and programs at Region 6. This QMP is a public document that contains operations specific for EPA Region 6. Programs and/or activities specifically for EPA Region 6 are noted within the QMP.

Concurrences

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Title: Acting Region 6 Quality Assurance Manager

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October 20, 2020

(Signature) (Date)

Office of Mission Support

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Title: Chief Information Officer & Deputy Assistant Administrator for Environmental Information
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Glossary of Acronyms

ANSI	American National Standards Institute
ARA	Assistant Regional Administrator
ASQ	American Society for Quality
BEACH	Beaches Environmental Assessment and Coastal Health Act
CAA	Clean Air Act
CFR	Code of Federal Regulations
CLP	Contract Laboratories Program
CO	Contracting Officer
COR	Contracting Officer Representative
CWA	Clean Water Act
CWPPRA	Coastal Wetlands Planning, Protection and Restoration Act
DQA	Data Quality Assessment
DQAO	Division Quality Assurance Officer
DQO	Data Quality Objectives
EI	Environmental Information
EPA	U.S. Environmental Protection Agency
EPAAG	EPA Acquisition Guide
EPAAR	EPA Acquisition Regulation
EQMD	Enterprise Quality Management Division
ERRS	Emergency Response Removal Services
ESAT	Environmental Services Assistance Team
FAR	Federal Acquisition Regulations
FR	Funding Recommendation
IGMS	Integrated Grants Management System
IQG	Information Quality Guideline
IRM	Information Resource Management
ISO	International Organization for Standardization
IT	Information Technology
LAN	Local Area Network
MSR	Management System Review
OEIP	Office of Enterprise Information Programs
OITO	Office of Information Technology Operations
OMS	Office of Mission Support
OPA	Oil Pollution Act
PC	Personal Computer
PE	Performance Evaluation
PT	Proficiency Testing
QA	Quality Assurance
QAM	Quality Assurance Manager
QA MOU	Quality Assurance Memorandum of Understanding
QAPP	Quality Assurance Project Plan
QAARWP	Quality Assurance Annual Report and Work Plan
QAFAP	Quality Assurance Field Activities Procedure
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Assessment
QTRAK	Quality Assurance Tracking System
RA	Regional Administrator
RAC	Remedial Action Contract

RAF	Remedial Action Framework
RCRA	Resource Conservation and Recovery Act
RFC	Request for Correction
RFR	Request for Reconsideration
RQAM	Regional Quality Assurance Manager
SDWA	Safe Drinking Water Act
SOP	Standard Operating Procedure
START	Superfund Technical Assistance and Response Team
TMDL	Total Maximum Daily Load
TSA	Technical Systems Audit
URL	Uniform Resource Locator
WIIN	Water Infrastructure for Improvements to the Nation Act

1. MANAGEMENT AND ORGANIZATION

1.1 EPA Mission

The mission of EPA is to protect human health and the environment to the extent outlined by Congress with the tools that are given to it by Congress and the other branches of government. Environmental impacts can be significant statistically, significant to the environment and/or significant to society; EPA only decides whether the first two conditions apply. Other parties, such as Congress, the Executive Branch, the Courts or the public, decide if the last condition applies. A good decision for EPA is one that follows both the spirit and letter of environmental law and regulations, protects the environment and public health, expends the least amount of resources, and is made in a timely manner. Decisions made by EPA **shall**[1] be based on valid scientific assumptions and good **information** because those decisions impact not only the environment but also public health, the regulated community and EPA's credibility.

Appropriate advanced planning is required to make sure that information collected will allow EPA to make a good decision. Good decisions that are made in a timely manner can save time, damage to the environment and/or the public health, lost resources, unnecessary litigation and EPA's credibility. The success of EPA fulfilling its decision-making mission depends on its ability to obtain information about the environment (**data**). The "**quality**" of the information used by EPA and the resources expended to obtain that information should be commensurate with the impact of the decision. The resources used to generate data can be measured with a great deal of **precision**, but the "quality" of data is not easily determined.

1.2 Quality Assurance

Quality Assurance (QA) is an integrated system of management activities (planning, implementation, **assessment**, reporting, and quality improvement) that focuses on providing confidence in the data or **product** by ensuring that it is of the type and worth needed and expected by the client. To ensure that **decision-makers** in EPA have the information that they need to make proper decisions, EPA Order CIO 2105.0, Policy and Program Requirements for the Mandatory Agency-wide Quality System (May 5, 2000) was issued. This order requires the establishment of a QA Program at EPA. EPA Order CIO 2105.0 tasked each EPA Regional Administrator (RA) to set up a QA Program. This **Quality Management Plan** (QMP) establishes **policy** and program **requirements** for the conduct of all **work** that generates **environmental data** performed by or for this agency within Region 6.

[1] See Appendix A for the definition of words and phrases that appear in **bold** in the text of this document.

1.3 Quality Management

As a matter of policy, Region 6 is strongly committed to good science and sound QA practices. The **integrity** of our science is a vital component of the Agency's work to fulfill our mission to protect public health and the environment. Indeed, the foundation of our decision-making relies on our ability to generate high-quality, irreproachable data from both our laboratories and from our field activities, as well as work performed by grantees or contractors on our behalf. Region 6 is committed to ensuring that staff are properly trained and provided the necessary resources to maintain an effective quality management program. Doing so reduces potential vulnerabilities in critical decision-making and helps protect the Agency's scientific integrity.

1.4 QA Structure

The Region 6 organizational structure, as shown in Figures 1 and 2, is headed by the RA, Deputy Regional Administrator (Deputy RA) and their staff (June 2020). There are eight Divisions, each headed by a Director as shown in Figures 3 through 10. The Region 6 **Quality System** is overseen by the **Regional Quality Assurance Manager (RQAM)**, who maintains independence from environmental data operations and is afforded access to the RA and/or Deputy RA, if needed. The independence of the **Quality Assurance Staff (QA Staff)** and other delegated representatives is not only required by national EPA policy, but is vitally important to the Region's implementation of its Quality System, allowing the RQAM the authority to advocate the importance and relevance of quality in EPA's work. The RQAM must be able to serve without any potential conflicts of interest due to his/her location in the Laboratory Services and Applied Sciences Division and remain outside of any sub-group that collects and/or uses environmental data directly.

Functionally, Region 6 has a centralized QA System. This centralized QA System consolidates the QA decision-making, assessment (auditing), guidance, and training functions in a central core, yet allows delegation of authority for day to day QA activities. The centralized QA System has the QA Group that resides in the Laboratory Services and Applied Science Division. This includes the RQAM, Regional Field Quality Manager, QA Coordinator, Regional QA Officers and the QTRAK Administrator. The Region 6 QA System relies on each Division and/or program office to be responsible for its own QA efforts identified in this QMP. Historically, the Region 6 QMP utilized Divisional QMPs to document the QA processes performed by the Division programs and respective Division Quality Assurance Officers (DQAOs). Region 6 established the August 2017 QA Memorandum of Understanding (QA MOU) (Appendix B) to provide a framework in defining Roles and Responsibilities of the RQAM and Divisions and their respective managers. The Region has realigned and centralized the QA System removing the Region 6 Divisional QMPs and DQAOs from this QMP. Since the August 2017 QA MOU has yet to expire, the applicable roles and responsibilities are addressed in this QMP. The Air and Radiation Division, Mission Support Division, Enforcement and Compliance Assurance Division, Laboratory Services and Applied Science

Division, Land Chemical and Redevelopment Division, Superfund and Emergency Management Division, and the Water Division are hereinafter referred to as the Programmatic Divisions in this QMP. The RQAM shall support the QA needs of the Programmatic Divisions and the Office of Communities, Tribes and Environmental Assessment and the Office of Regional Counsel (hereinafter referred to as Offices). This QMP uses the EPA Region 6 mail codes to identify the Programmatic Divisions or Offices and corresponding program QA activities.

Duties assigned to the QA Staff, specifically the RQAM, the delegated in this QMP, and subordinate Quality System Documents shall be consistent with EPA Order CIO 2105.0, which states in part in paragraph 7d, "If these personnel have other functions to perform, there shall be no conflict of interest" with their QA duties and responsibilities. The QA Staff should not be assigned direct project management duties, especially if the **project**(s) involves generation of environmental data. If QA Staff are assigned direct project management responsibilities, the supervisor of the individual shall prepare a plan that includes a clear statement of who has approval and oversight authority for the technical activities. This plan shall be submitted to the RQAM for approval prior to initiation of any project related activities.

This Region 6 QMP covers the delegation of QA responsibility to the Programmatic Divisions and Offices, the responsibilities of the RQAM and his/her oversight of QA and the interactions between the RQAM and the Region 6 Divisions and Offices. The RQAM is ultimately responsible for assuring the **independence** of QA staff of the Region and shall attempt to assure there is an effective amount of operational independence for all QA staff. Where this independence may be lacking, the RQAM will perform assessment and oversight of the affected projects or delegate, with management approval.

Figure 1: Region 6 Office of the Regional Administrator Division Standard Functions – June 2020

Figure 2: Office of the Regional Administrator Standard Functions – June 2020

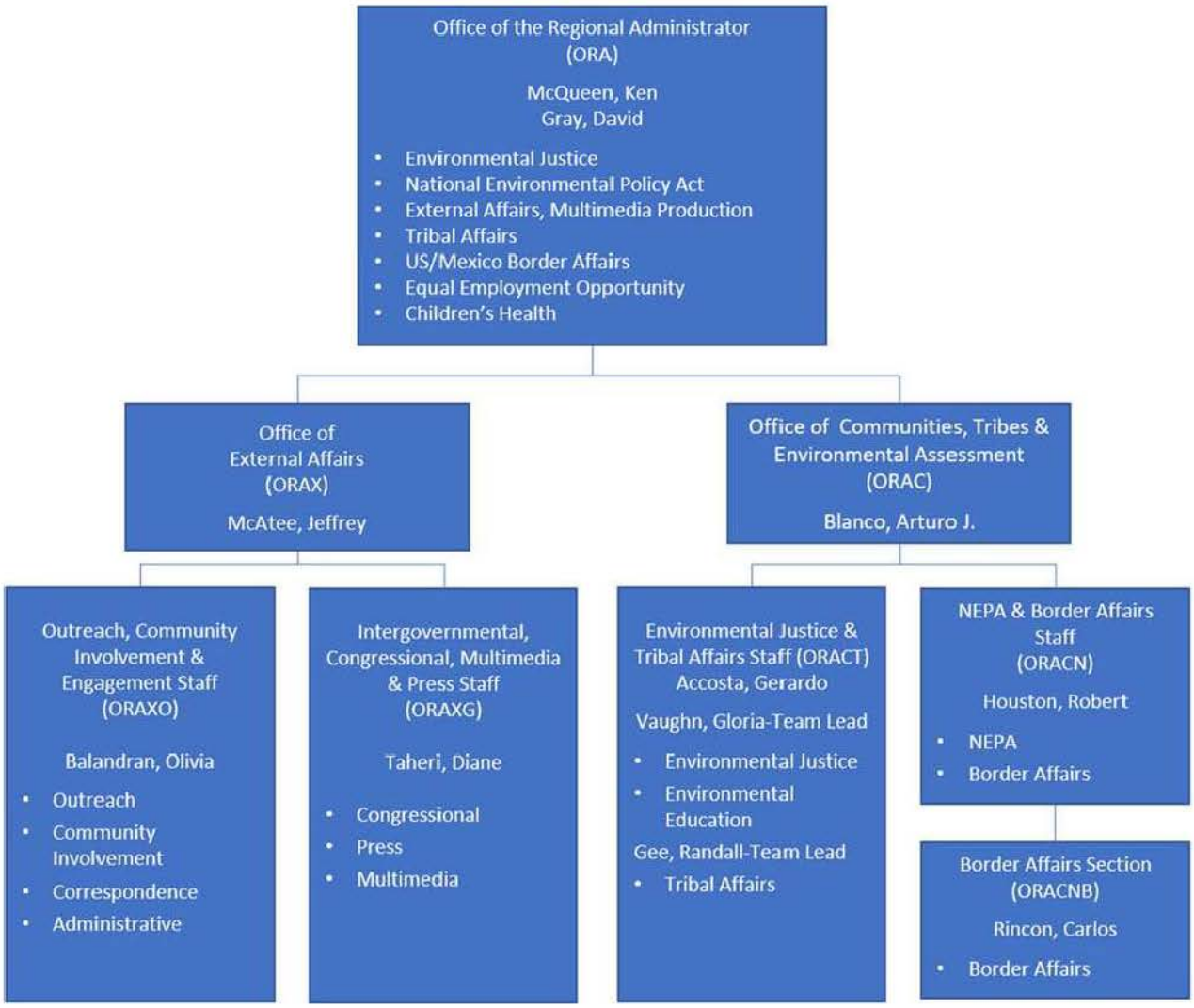


Figure 3: Air and Radiation Division Standard Functions – June 2020

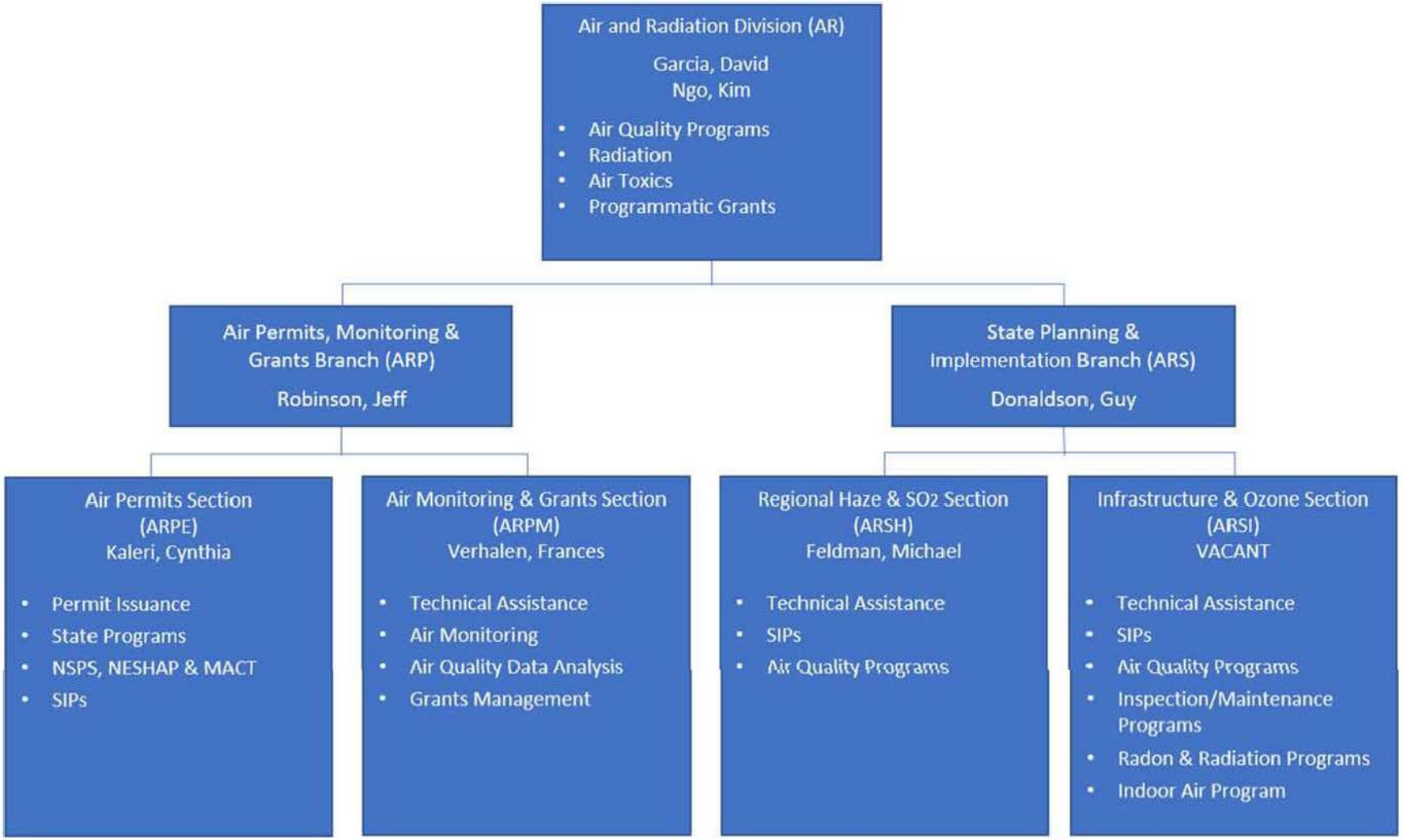


Figure 4: Mission Support Division Standard Functions (Administration and Resources Management) – June 2020

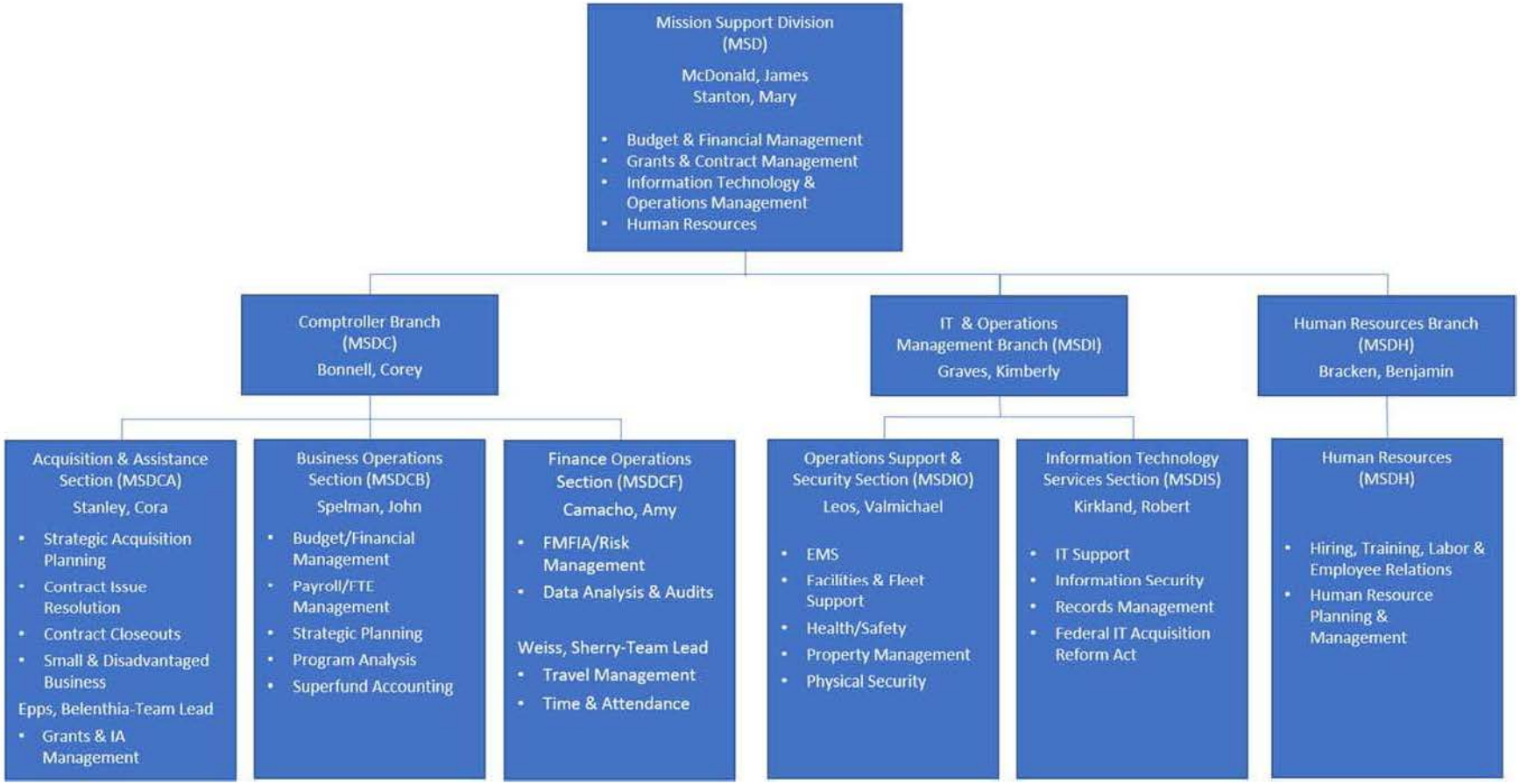


Figure 5: Enforcement and Compliance Assurance Division Standard Functions – June 2020

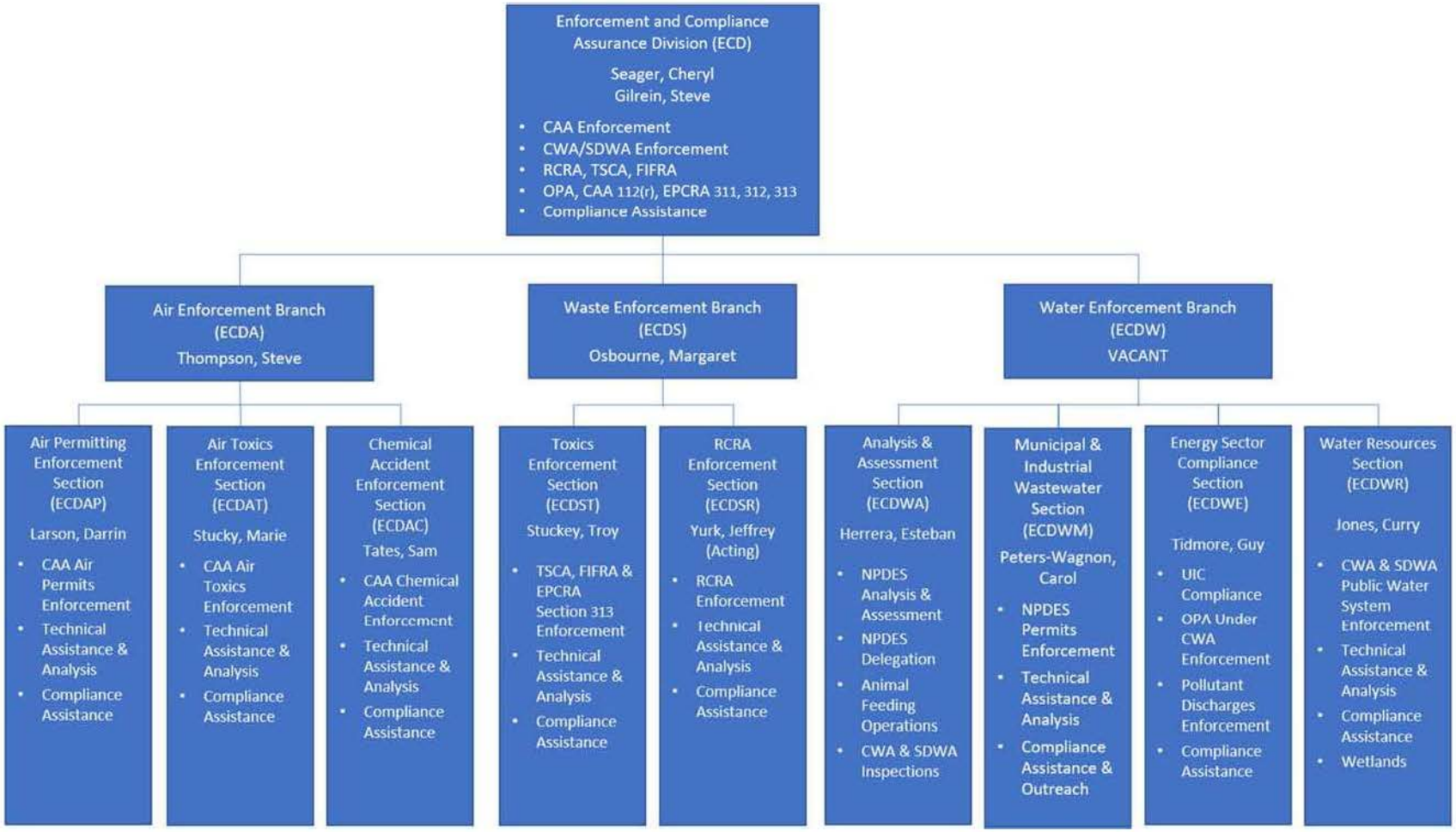


Figure 6: Laboratories Services and Applied Science Division Standard Functions and QA lines of communication – June 2020

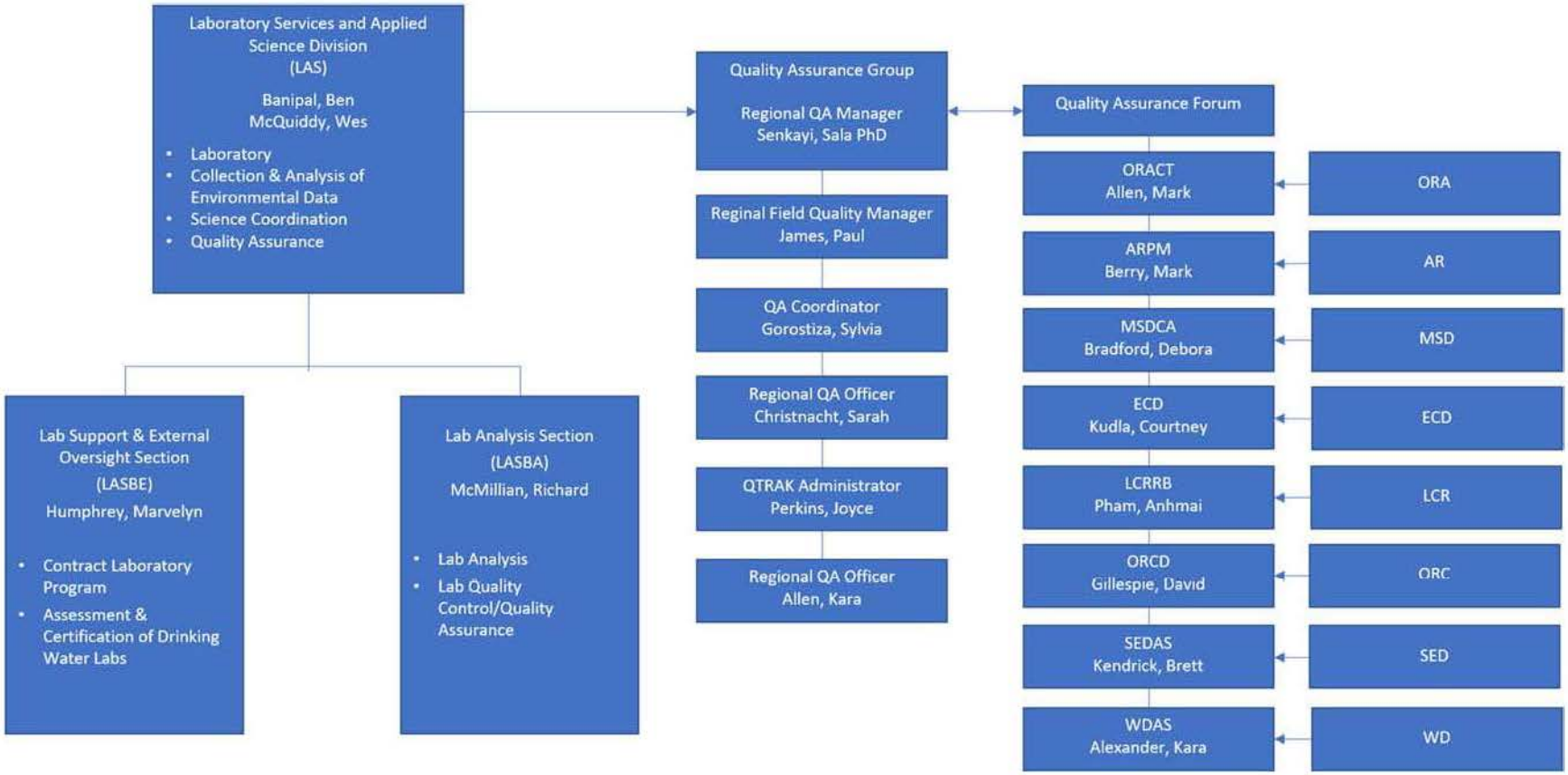


Figure 7: Land, Chemical and Redevelopment Division Standard Functions – July 2020

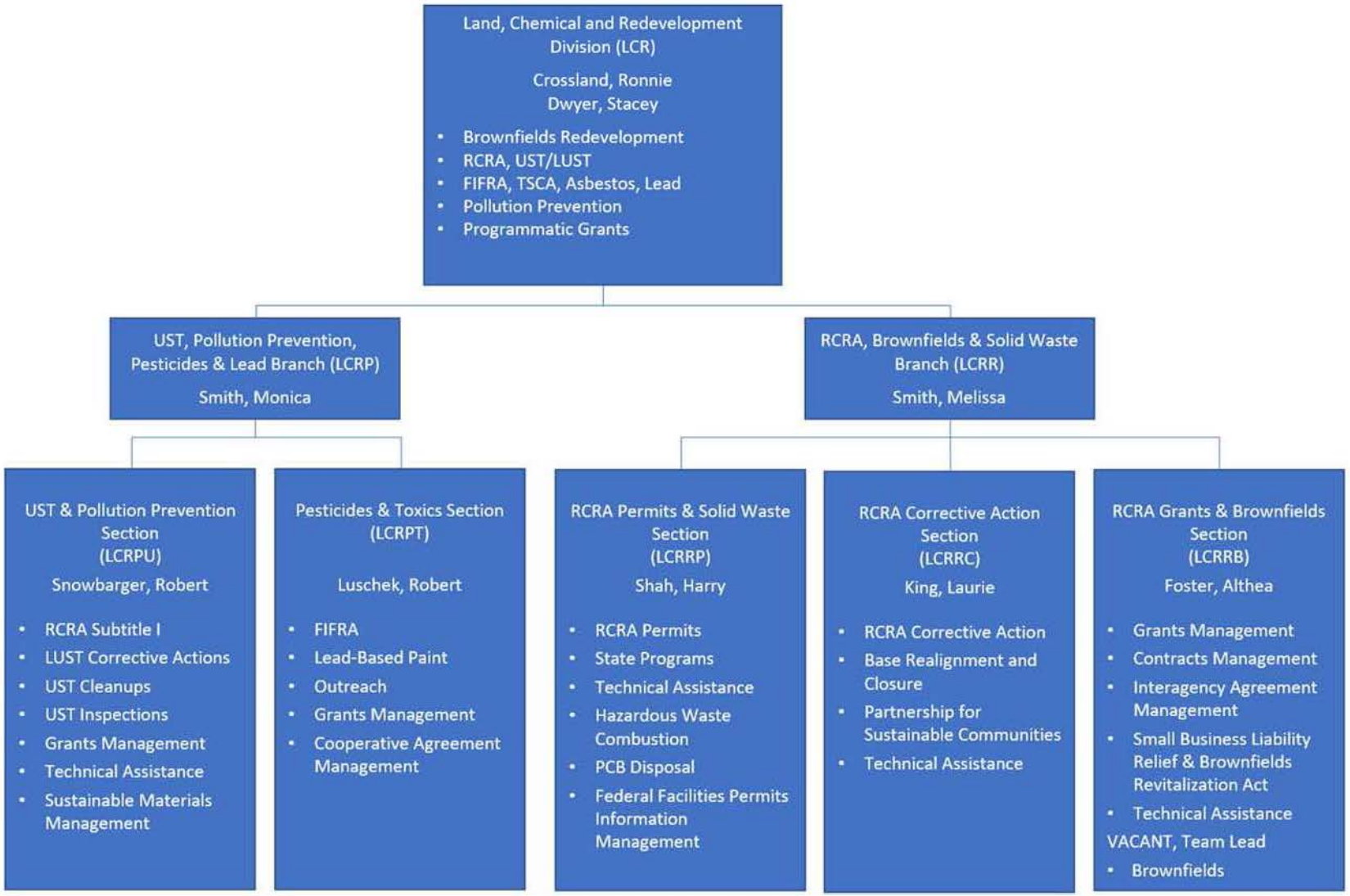


Figure 8: Office of Regional Counsel Standard Functions – August 2020

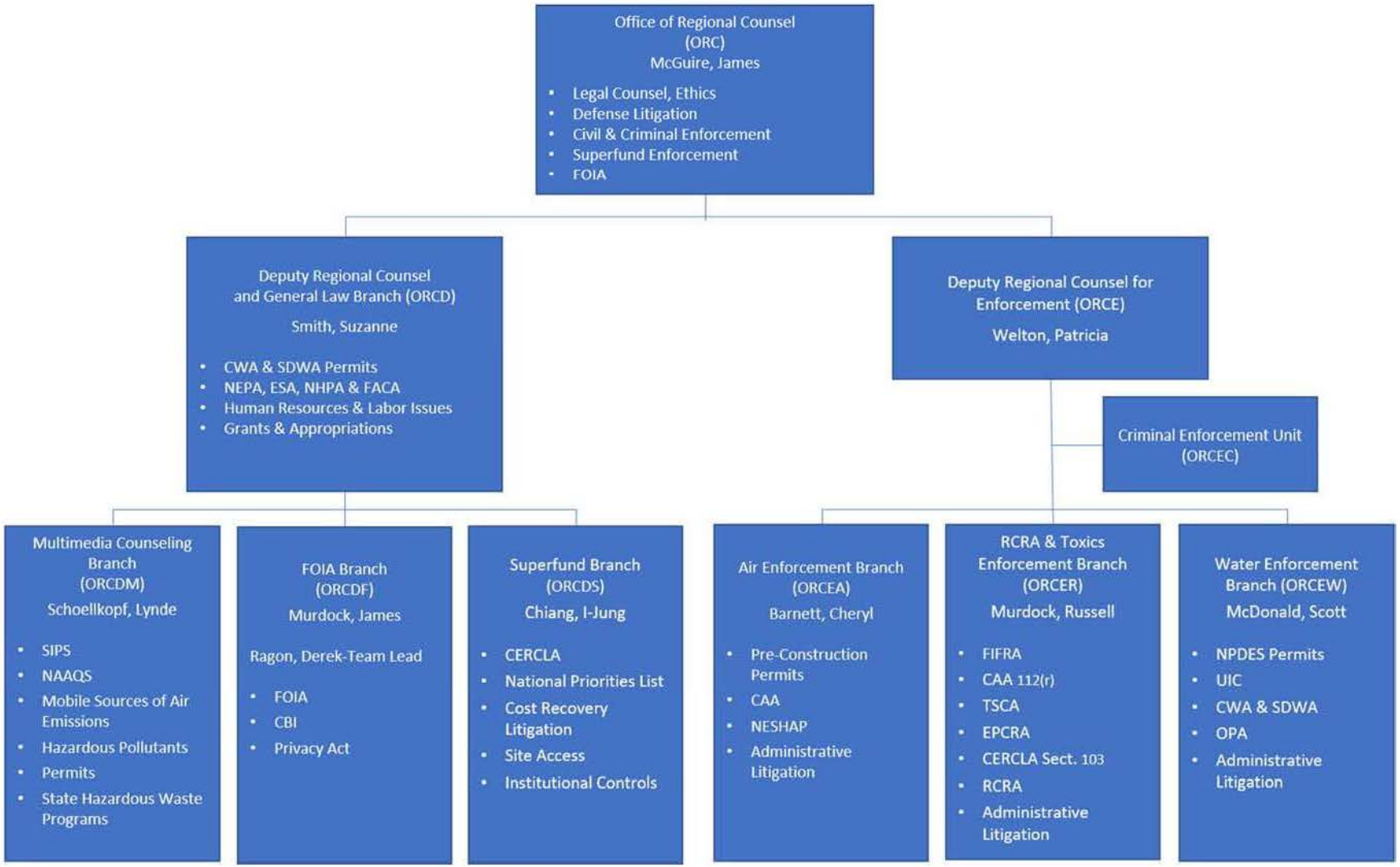


Figure 9: Superfund and Emergency Management Division Standard Functions – June 2020

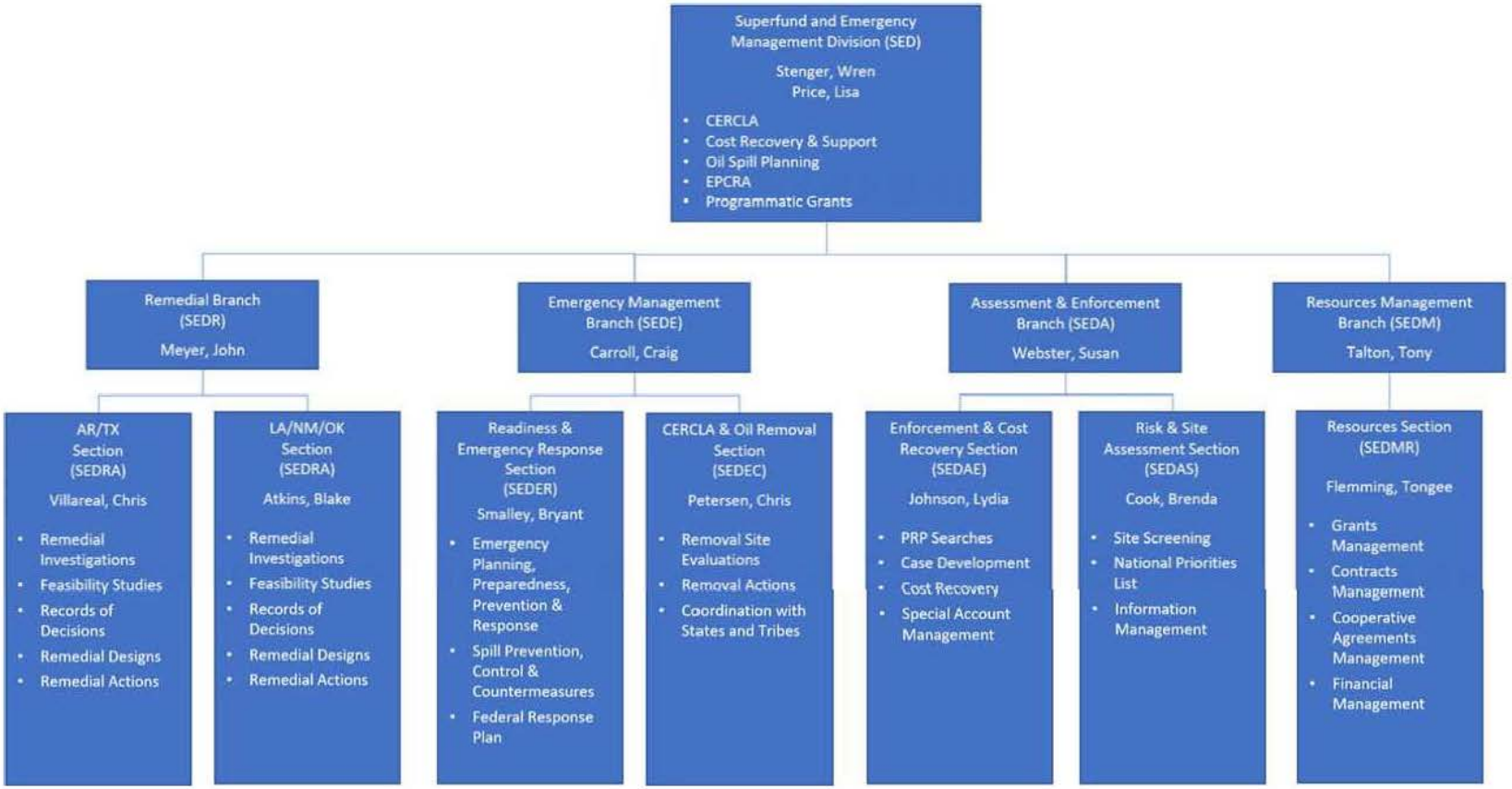
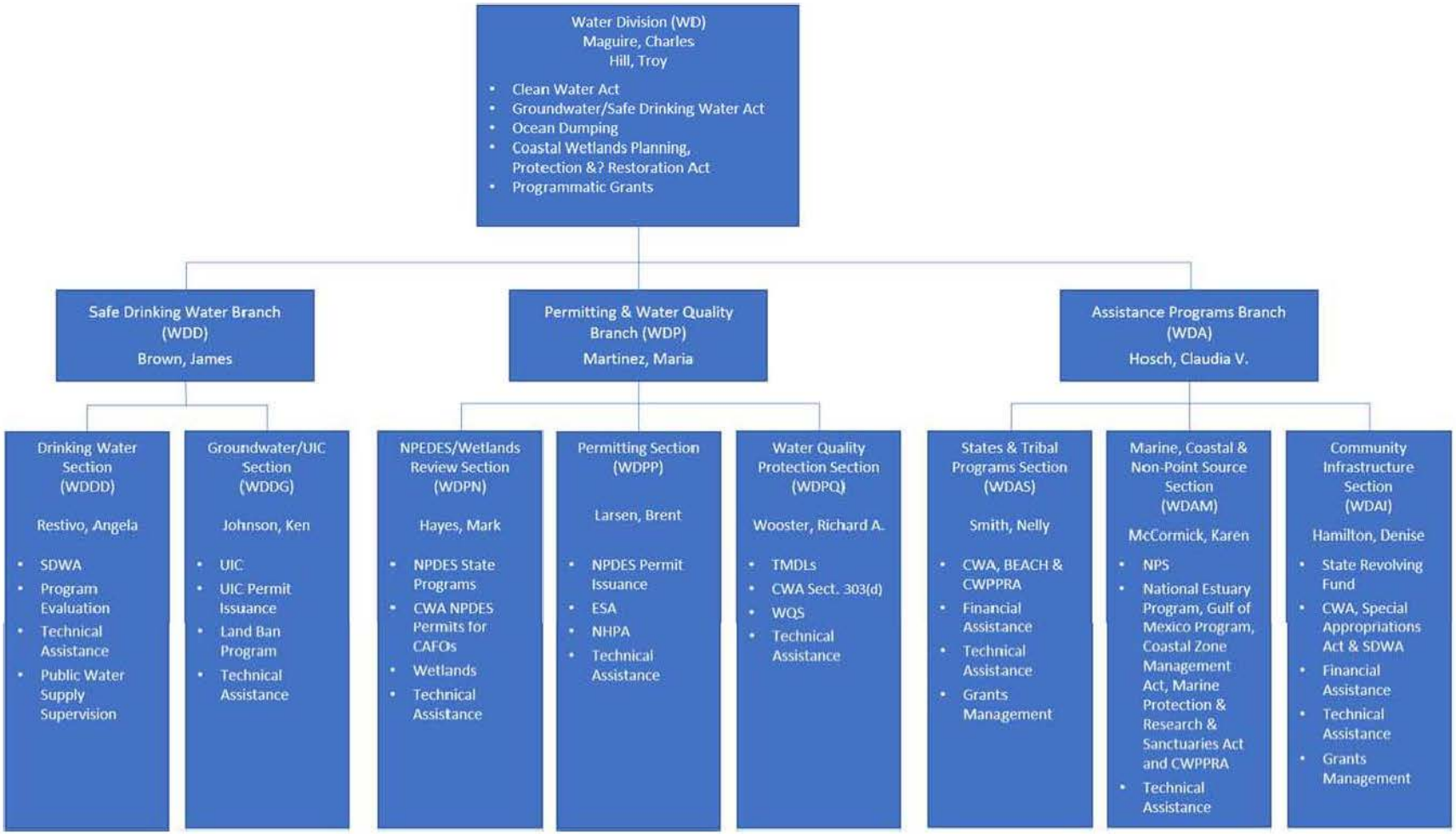


Figure 10: Water Division Standard Functions – June 2020



1.5 Effective Date of QA Documents

This QMP becomes effective on the date signed as **approved** by the RA or his/her delegated and expires 5 years from the date signed, unless a shorter period is specified. External QMPs submitted to Region 6 for approval become effective when signed as approved by the RQAM and expire no later than 1 year from the date signed, unless a shorter period is specified.

Specific programmatic requirements that are expressed to external customers, such as grantees or contractors, may stipulate a shorter time period, or require submission by a specific time as a condition of a grant or contract. This more specific requirement does not take precedence over the one-year maximum general requirement.

Quality Assurance Project Plans (QAPPs) become effective on the date they are signed as approved by the Project Officer, and expire between 1 and no more than 3 years from the date signed, unless otherwise stated by the Programmatic Division or Office and approved by the RQAM. The approval period shall be defined in the approval notification. For data collection projects that are expected to be completed in less than 18 months, the QAPP will normally be approved for the life of the project. For those data collection projects expected or planned to last longer than 18 months, QAPPs will usually be approved for a period not to exceed three years, if the QAPP meets all the technical and program requirements. The QAPP approval period can be less than three years, if the QAPP would need to be revised to include missing technical or program goal requirements. A reduced approval period can be recommended by the technical reviewer or the Project Officer. This QMP specifies the delegated approving official, **process** and expiration terms for Region 6.

Quality Assurance Manuals (QA Manuals) become effective on the date they are signed as approved by the QA Coordinator or delegated approving official and expire 5 years from the date signed, unless a shorter period is specified.

Standard Operating Procedures (SOPs) become effective on the date they are signed as approved by the delegated approving official, unless otherwise stated in the document. The SOPs expire 5 years from the effective date, unless a shorter period is specified.

1.6 Scope

As required by Title 2 Part 1500.11, Title 40 Part 35 and Title 48 Part 46 of the Code of Federal Regulations (CFR), this QMP covers the activities of the following programs (designated by Region 6 mail code): EPA grants, cooperative agreements, interagency agreements or contracts, and any other entity performing work that generates environmental data funded by or used by the EPA for decision-making.

OFFICE OF COMMUNITIES, TRIBES & ENVIRONMENTAL ASSESSMENT	MAIL-CODE
U.S. Mexico Border 2020	(ORACN)
Tribal General Assistance Program	(ORACT)
Environmental Justice Small Grant Program	(ORACT)
Environmental Education Program	ORACT)

AIR AND RADITION DIVISION PROGRAMS	MAIL-CODE
Air Emissions Inventory	(ARSI)
Air Modeling	(ARPE, ARSH)
Ambient Air Monitoring	(ARPM)
Grants 103 (Air)	(ARPM)
Grants 105 (Air)	(ARPM)
Radon Action Programs	(ARSI)
State Implementation Plans (Air)	(ARSH, ARSI)

MISSION SUPPORT DIVISION PROGRAMS	MAIL-CODE
Geographic Information Systems	(MSDIS)

LABORATORY SERVICES AND APPLIED SCIENCE DIVISION PROGRAMS	MAIL-CODE
Environmental Services Assistance Team (ESAT)	(LASBE)
Laboratory	(LASBE, LASBA)

LAND, CHEMICAL AND REDEVELOPMENT DIVISION PROGRAMS	MAIL-CODE
Brownfields	(LCRRB)
Pesticides Program Implementation	(LCRPT)
RCRA Corrective Action	(LCRRC)
RCRA Facility Assessment	(LCRRP)
RCRA Federal Facilities	(LCRRP)
RCRA State and Tribal Oversight	(LCRRP)
RCRA Strategic Planning and Information Management	(LCRRP)
Solid Waste Program	(LCRRP)
Underground Storage Tank Program	(LCRPU)

SUPERFUND AND EMERGENCY MANAGEMENT DIVISION PROGRAMS	MAIL-CODE
Emergency Response Removal Services (ERRS)	(SEDER, SEDEC)
Geographic Information Systems	(SEDMR)
Hazardous Spill & Site Response	(SEDER)
Oil Pollution Act (OPA)	(SEDEC)
Remedial Action Contract (RAC)	(SEDMR)
Remedial Action Framework (RAF)	(SEDMR)
Remedial Activities	(SEDRA, SEDRL)
Response Activities	(SEDER)
Site Assessment	(SEDAS)

Superfund Cooperative Agreements (Remedial) ..... (SEDMR)
Superfund Technical Assistance & Response Team Contract (START) ..... (SEDMR)

ENFORCEMENT AND COMPLIANCE ASSURANCE DIVISION PROGRAMS	MAIL-CODE
Air Enforcement Program	(ECDA)
Waste Enforcement Program	(ECDS)
Water Enforcement Program	(ECDW)

WATER DIVISION PROGRAMS	MAIL-CODE
Assessment, Listing and TMDL Section	(WDAS, WDPQ)
Beaches Environmental Assessment and Coastal Health Act (BEACH)	(WDAS)
Coastal Wetlands Planning, Protection and Restoration Act (CWPPRA)	(WDAS, WDAM)
Gulf of Mexico	EPA Region 4
National Estuary Program	(WDAS, WDAM)
Non-Point Source (319)	(WDAS, WDAM)
Ocean Dumping	(WDAM)
Pontchartrain Restoration Program	(WDAS, WDAM)
Public Water Supply Supervision	(WDAI, WDDD)
Special Appropriation Act Projects	(WDAI)
State Revolving Funds (CW & DW)	(WDAI)
Total Maximum Daily Load (TMDL)	(WDAS, WDPQ)
US/Mexico Border Program	(WDAI)
Urban Waters	(WDAS)
Underground Injection Control	(WDAI, WDDG)
Water Pollution Control (106, Ground Water)	(WDAS, WDDG)
Water Quality Management Planning 604(b)	(WDAS)
Water Quality Standards	(WDAS, WDPQ)
Wetland Program Development	(WDAS, WDPN)
Water Infrastructure for Improvements to the Nation (WIIN) Act (5-yr authorization in 2017 to support Gold King Mine monitoring)	(WDAI)

In compliance with EPA QA Field Activities Procedure, CIO 2105-P-02.0, September 23, 2014, (QAFAP), Region 6 defines the scope of field activities to mean activities requiring the collection of environmental observations, samples or data in support of EPA programs, Executive Orders, regulations or environmental laws at a site or location. The QAFAP is an EPA only and internal procedure for EPA personnel to observe and follow for field related activities.

1.7 QMP Policy

EPA prefers QMPs that adequately cover the most programs as consistently as possible. A single QMP, covering multiple QAPPs, will maximize the consistency of efforts, and minimize the systemic variation in those QAPPs. However, each State or State Agency, Municipality,

University or Nonprofit Organization, Tribal Grantee and Contractor may develop as many QMPs as they feel are necessary. The QMPs shall follow the **guidance** of Chapter 3 of the EPA Quality Manual for **Environmental Programs** CIO 2105-P-01-0 for EPA organizations, or the current EPA Requirements or Guidance Documents as applicable for non-EPA organizations. Current and approved QMPs shall be on file with the Region 6 RQAM before an application for EPA **financial assistance** is considered complete (See Paragraph 1.11 for additional information).

1.8 QMP Submittal, Review and Extension Procedures

Region 6 QMP

Revision of this QMP will be processed through the QA Forum and each Division Director for concurrence prior to being submitted to the RA for approval. The Laboratory Services and Applied Science Division, through the RQAM, agrees to take the lead in accomplishing these revisions. The Programmatic Divisions and Offices agree to support the accomplishment of these revisions and their roles and responsibilities identified in this QMP through their QA Forum members as stated in Section 10.2. The Region 6 QMP will be reviewed to meet the effective date/requirements of Section 1.5.

External QMPs

Approval or disapproval and return of a QMP to the submitting grantee or prospective grantee will be accomplished within 30 calendar days by the RQAM or delegated. Specific written comments shall be provided when a QMP is disapproved which assist the submitter in creating a workable QMP. In lieu of written comments, at the discretion of the RQAM, verbal or electronic feedback may be provided to the submitter of a QMP if the submitter prefers comments in that manner. If working with a QMP submitter to revise a non-conforming QMP, then the RQAM needs to assure that revised QMPs are submitted in a timely manner to not exceed the 30 calendar day time-frame. QMP reviews may be accomplished by the QA Staff; however, final approval/disapproval is the sole responsibility of the RQAM.

The review of QMPs submitted by contractors or prospective contractors may be accomplished by the Programmatic Division or Office as an assistance to, the responsible Contracting Officer (CO) or Contracting Officer's Representative (COR) as described in the EPA Acquisition Guide (EPAAG). If applicable, this Programmatic Division support is due to separate funding allocations. Each Programmatic Division or Office will follow and accomplish all requirements defined in Chapter 46 of the EPAAG for the RQAM. If any Programmatic Division or Office defines a QA Review Form that differs from the one that is in Chapter 46 of the EPAAG, that form shall be appended to this QMP, after approval by the RQAM and the CO or COR sign off on the QA Review Forms.

Once a grantee's QMP has been reviewed and approved, its expiration date is set at one year

from the date of approval per Section 1.5 of this QMP. A Project Officer may request that the RQAM extend the expiration date of a previously approved QMP. If the RQAM grants this extension request, the extension shall not exceed a period of 18 months from the date of the initial approval. Extensions beyond 18 months after initial approval date require the concurrence of the RQAM and a decision by the Division Director for Laboratory Services and Applied Science. Any changes to expiration dates require annotation in the Comments Section of **QTRAK** (Quality Assurance Tracking System) (further described in Section 1.11) regarding details of the extension and revising the expiration date. Regardless of the length of an extension to a QMP, when an updated QMP from the same organization is submitted, the annual approval period for the new QMP shall begin on the date the extended QMP was originally set to expire.

A full QMP submittal package is not required every year. The grantee must review the QMP at least annually to confirm the effectiveness of the approved quality management practices. If there are essentially minor updates as identified in the agency's QMP, then only a letter stating those changes (if any) and signed signature sheets are needed. This can be submitted electronically so as to comply with the Paperwork Reduction Act.

A revised QMP may be submitted at any time, but it is required under certain conditions as identified in EPA Order CIO 2105-P-01-0. This includes an expiration on the fifth year of the full submittal QMP approval or a major reorganization. Having an accurate QMP is an essential element in every quality system. Changes in QA policy and procedures shall be documented in a timely fashion by QMP revision(s).

1.9 QMP Reciprocity

If an external organization has a QMP that has been approved by another EPA Organization (i.e. Region, Program Office, ORD Laboratory, etc.), it can be accepted reciprocally by EPA Region 6 as an approved QMP under certain conditions.

QA Staff shall be able to verify the approval period or expiration date of the QMP, and that the EPA organization previously approving the QMP actually did approve it. The decision to accept a QMP under reciprocity may include a recommendation to do so from the applicable Programmatic Division or Office, but it only requires approval by the RQAM. If provided, the recommendation should assure the QMP adequately covers the type of work being performed and make a statement regarding the length of the approval period for Region 6 use. The request for reciprocity may come directly from the external organization without a recommendation. The external organization seeking reciprocal approval shall provide a copy (original copy if available) with signatures of the QMP for the files and a QTRAK number shall be assigned for the purpose of **traceability**. The name of the original EPA approver, their organization, date of approval and length of approval shall be obtained and entered into QTRAK. The Region 6 Project Officer's name will be entered into QTRAK as the Project Officer for the QMP. The Project

Officer from the original EPA organization that approved the QMP shall be entered in the comments section of QTRAK.

1.10 QAPP Submittal Review and Extension Procedures

In addition to a QMP, Title 2 CFR Part 1500.11, Title 40 CFR Part 35 and Title 48 CFR Part 46 require that all **environmental data operations** performed by or for (with resources supplied by the Agency or for Agency decision-making) EPA be described in an approved QAPP or **equivalent document**. Determination of a **document** being equivalent to a QAPP shall be accomplished jointly by the Programmatic Division or Office subject matter expert and the Project Officer. If an approved QMP from the submitting organization exists that defines a process for development of an equivalent document in lieu of a QAPP, then no consultation is required. The review and approval of QAPPs, both internal and external, is a responsibility delegated to each Programmatic Division or Office as described in this QMP (See Section 2.3 and 5.1). This QMP also stipulates the process used to assure that QAPPs are current. Any proposed change in an approved QAPP shall be approved by the same process as the initial approval unless otherwise specified in this QMP (See Section 2.3 and 5.1). QAPPs shall follow the requirements of the Office of Mission Support (OMS)/Environmental Information (EI), Office of Enterprise Information Programs (OEIP), Enterprise Quality Management Division (EQMD) for QAPPs, designated as EPA Requirements for Quality Assurance Plans, EPA QA/R-5 for external extramural QAPPs and Chapter 5 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0 for internal QAPPs. An approved QAPP is required to be in place prior to the beginning of environmental data operations, except in situations requiring immediate action to protect human health and the environment or operations conducted under police powers. Any entity receiving funds from EPA that does not perform environmental data operations may be exempted from the requirements for a QMP and QAPP, but only by the RQAM. All QAPPs shall be fully implemented and follow the process by which implementation will be verified (See Section 8.1). Oversight of implementation for the Region shall be accomplished during QA **Management System Reviews** (MSR) or Quality System Assessments (QSA) as covered in Section 9 and performed under the direction of the RQAM.

All QAPPs for continuing programs will be revised when the previous QAPP expires and submitted to the Project Officer 60 calendar days prior to the expiration date. Provided the revised QAPP is submitted as outlined in Section 5, the previously approved QAPP shall remain in force until the revised QAPP receives approval, allowing any data collection activities to proceed uninterrupted until subsequent approval of the revised QAPP by Region 6.

However, for those data collection projects expected to last longer than 18 months, all such QAPPs shall be reviewed and revised as appropriate at least once each year by the applicable grantee, contractor or project manager, in the case of internal projects. If no revisions are necessary to the QAPP, because no substantive technical or programmatic changes have

occurred in the project, a letter (stating that no changes are necessary) shall be submitted to the Project Officer. This item can be submitted electronically so as to comply with the Paperwork Reduction Act. If substantive changes have been made to the project which affects the performance of work for the Agency/Region 6, then the grantee must revise and resubmit the entire QAPP for approval. The Project Officer must also examine the QAPP or consult with the technical reviewer annually to make sure no significant changes have occurred in the project that would require a technical or programmatic review, revisions to the QAPP and subsequent approval by EPA. Records of correspondence shall be maintained by the Project Officer in the grant file (see Section 5.3). A QAPP must be revised and resubmitted in the following cases:

- The QAPP has expired after the three-year life span;
- The project has major changes to project/program goals or changes in the technical approach to meet those goals or
- The project has changes in roles and/or responsibilities of the project leaders.

During the technical review, the technical reviewer may communicate directly with the submitting agency to resolve technical, grammatical or format problems with a QAPP, but these communications must be relayed to the Project Officer. The technical reviewer should meet the training requirements in Section 3. To resolve programmatic concerns in a QAPP, the Project Officer will consult with the technical reviewer before contacting the submitting agency.

Once a QAPP has been reviewed and approved, its expiration date is set per Section 1.5 of this QMP. Expiration dates of QAPPs may be extended if a valid reason to do so exists and the data from the project would not be impaired. An example of a valid reason for extending a QAPP expiration date would be the temporary non-availability of a key person that writes, reviews or approves the QAPP. Each Division and Office will assure that QAPP extensions are requested for a specific valid reason and that the approval of the RQAM has been obtained. If the QAPP expiration date is extended, the extension shall not exceed a period of 6 months unless approved by the RQAM. Any changes to expiration dates will require annotation in the Comments Section of QTRAK regarding details of the extension to include addressing the compelling reason an extension is needed and revising the expiration date. These QTRAK changes shall be sent via email from the Project Officer to the RQAM and QTRAK Administrator to assure the extension is approved.

1.11 QAPP and QMP Tracking

Region 6 has developed a database called QTRAK for recording, tracking and identifying quality documents. All QMPs shall be submitted to the RQAM for approval and to receive a tracking number. QAPPs are not required to be submitted to the RQAM; however, information regarding the QAPPs shall be provided to the RQAM, or QTRAK Administrator, in order to receive a tracking number. The QTRAK Administrator issues a tracking number (QTRAK number) for each QA

document in QTRAK. The RQAM can also assist and issue a tracking number. The Project Officer or COR request a QTRAK number using a QTRAK request form. The form is electronically submitted to the QTRAK Administrator for review and issuance of the QTRAK number. The QTRAK Administrator maintains the blank QTRAK request form. The tracking number is a required entry on the QA Certification Form that is addressed in Section 1.12. Grantee QMPs and QAPPs shall be tracked to assure timely review, approval or re-submission and to inform internal and external customers of the status of any QA plan at any time. Submission of a QMP or a QAPP to EPA Region 6 from a grantee requires a response, preferably written or at least electronic, acknowledging receipt or notifying the grantee of approval along with providing the tracking number to the grantee. Responses are the responsibility of the individual at Region 6 that receives and/or approves the QMP or QAPP.

1.12 QA Certification Form Process for Integrated Grants Management System (IGMS)

The Project Officer has primary responsibility for ensuring QA requirements are satisfied for EPA's financial assistance agreements. The Grants Specialist ensures QA documentation is included in each Funding Recommendation (FR) package. QA roles and responsibilities for both Project Officers and Grants Specialists are described in the Grants Specialist Training and Project Officer Training courses. Additional requirements, or changes to those requirements are defined by the Office of Grants and Debarment; definitions of roles and responsibilities take precedence over this regional document in regard to Grants Training. The RQAM works closely with the appropriate Project Officer to assure all required QA Documentation is present, current and approved prior to release of funds. This responsibility is discharged by a joint QA Certification Form (copy at Appendix C) signed by the Project Officer and RQAM. The RQAM will assure that an electronic copy of all signed QA Certification Forms is part of the permanent IGMS. The IGMS approval authority is exercised by the RQAM. RQAM's IGMS approval authority is retained within the grant's office under the Mission Support Division and assures independence of the QA review process. The RQAM will attempt to provide prompt responses to Project Officer's IGMS FR, but due to operational necessities of travel and other reasons of non-availability, may take as long as 5 working days to respond to the FR.

1.13 EPA Competency Policy

In August 2014, the Assistant Regional Administrator (ARA) issued a memo to all Divisions requiring Regional Staff to assure that Assistance Agreement Holders were in compliance with the EPA Competency Policy. The Competency Policy applies to all Assistance Agreement Holders with awards of $200,000 or greater during the life of the agreement.

This is accomplished by:

- Project Officers determining the grant is less than $200,000 (no action is required);
- Project Officers determining the grant is more than $200,000 then the

following actions are required.

- A statement must be added to the Organizations QA documents, specifically the Work Plans (in addition to the QAPPs or QMP if applicable -see Appendix C).
- Utilize the R6 Checklist for the Implementation of the FEM Policy for Competency for Grants and Cooperative Agreements (Appendix C) to determine implementation with the Agreement Holder.
- All Funding Recommendations must contain the following statement in the terms and conditions of the Cooperative Agreement and the QA Certification Form (see Appendix C) must be filled in appropriately:
  - In accordance with Agency Policy Directive Number FEM-2012-02, Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements, Recipient agrees, by entering into this agreement, that it has demonstrated competency prior to award, or alternatively, where a pre-award demonstration of competency is not practicable, Recipient agrees to demonstrate competency prior to carrying out any activities under the award involving the generation or use of environmental data.
  - Recipient shall maintain competency for the duration of the project period of this agreement.
  - A copy of the Policy is available online at URL https://www.epa.gov/sites/production/files/2015-03/documents/competency-policy-aaia-new.pdf or a copy may also be requested by contacting the EPA project officer for this award.

1.14 Regional Administrator and Senior Managers

The Division Director for Laboratory Services and Applied Science is the central management authority for this program. As described in the August 2017 QA MOU, the RA and Senior Managers shall:

1.14.1 Ensure that all Regional components and programs fully comply with the requirements of the EPA Order CIO 2105

1.14.2 Ensure that quality management is an identified **activity** with associated resources adequate to accomplish its program goals and is implemented as prescribed in this QMP

1.14.3 Ensure that all environmental programs implemented through extramural agreements comply fully with applicable QA and **quality control** (QC) requirements

1.14.4 Ensure that the environmental data from environmental programs

delegated to State, local and Tribal governments are of sufficient quantity and adequate quality for their intended use and used consistently with such intentions

1.14.5 Ensure the training is available for Regional employees, in addition to State, local and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA and QC activities that may be expected by EPA to perform

1.14.6 Perform periodic assessments of Regional organizations conducting environmental programs to determine the **conformance** of their mandatory quality systems to this QMP and the effectiveness of their implementation

1.14.7 Ensure that deficiencies highlighted in the assessments are appropriately addressed

1.14.8 Identify QA and QC training needs for all levels of management and staff and provide this training

1.14.9 Ensure that Regional resources are used effectively to achieve compliance with the QA/QC requirements imposed by EPA Order CIO 2105.0

1.14.10 Ensure a representative is delegated for the QA Forum meeting Section 10.3

1.14.11 Periodically it may be necessary to delegate an acting for the QA Forum to assure that Programmatic Division and Office QA functions are accomplished in a timely manner

1.15 RQAM

The RQAM and delegated staff will be responsible for the following QA activities (see Section 9 for explanation of these functions).

1.15.1 Review and approval of all QMPs and coordination of QMP reviews

1.15.2 Maintenance of the QMP and QAPP tracking system (QTRAK)

1.15.3 Oversight of EPA funded data generation through MSRs or QSAs

1.15.4 Training and **certification** of individuals delegated to write, review and/or approve QMPs or QAPPs or to process IGMS awards

1.15.5 QA specific technical assistance to the program offices, States, Municipalities, Nonprofit Organization and Tribal grantees on the preparation of QMPs and QAPPs

1.15.6 Developing and providing courses that train EPA, State, Municipal, Nonprofit

Organization and Tribal grantee staff in QA topics

1.15.7 Providing QA specific assistance to our customers both at and outside EPA

1.15.8 Providing assistance to our customers in the planning of projects that generate or use environmental data

1.15.9 Providing assistance to our customers in the development of environmental laws, rules and regulations

1.15.10 Review and approve exemptions for QA plan requirements for Grants, Cooperative Agreements and Interagency Agreements that do not involve Environmental Data

1.15.11 Review and approve QA certifications for Grants, Cooperative Agreements and Interagency Agreements that involve Environmental Data

1.15.12 Maintenance of a file system that contains an original copy, or electronic equivalent of an original copy of all the current QMPs

1.15.13 Development and implementation of Regional QA policy

1.15.14 Approval of QAPP expiration date extensions and notification to Project Officer and Programmatic Division and Offices Supervisor of such actions

1.16 Delegation of QAPP Approval Authority to Non-EPA Organizations

The delegation of QAPP approval authority to non-EPA organizations shall be accomplished on a case-by-case basis, with input from the RQAM, Project Officers and managers of the applicable Programmatic Division or Office.

1.16.1 QA Criteria - In order to be considered for QAPP approval delegation, an organization shall have had an approved QMP in place for at least 5 years prior to the proposed date of delegation. The delegation request shall indicate the measures the organization proposes to implement to assure their internal QA system produces and effectively reviews QAPPs and what oversight or assessment activities will be accomplished to verify adequacy of these measures during the life of the delegation. The QA Manager of the requesting organization shall concur with the delegation request.

1.16.2 QSA - In order to be considered for QAPP approval delegation, an organization shall have a QSA conducted of the organization by the EPA with participation by the independent QA element of the requesting organization. If either the EPA or the requesting organization has conducted a QSA or equivalent assessment within the past year, their participation is optional, provided that the results were deemed acceptable by the QA Managers of both organizations. The QSA shall verify that the requesting organization's quality system is in conformance

with its own approved QMP and with EPA Order CIO 2105.0 and that the quality practices of the organization are suitably and effectively implemented. This assessment shall be led by the RQAM or delegated with assistance from the applicable Programmatic Division.

1.16.3 Programmatic Criteria - In order to be considered for QAPP approval delegation, an organization shall have demonstrated a past history (5 years) of producing and internally reviewing QAPPs that assures a high level of technical competency is in place prior to the proposed date of delegation. Any limitations or exceptions to the proposed QAPP approval delegation shall be developed and coordinated among all affected programmatic managers and the Project Officers. Managers responsible for QAPP review shall assure this competency exists by review of previously submitted QAPPs.

1.16.4 Decision Criteria - In order to be delegated QAPP approval authority, joint concurrence by the RQAM, Project Officers and Programmatic Division of Office Management of the delegation proposal is required.

1.16.5 Delegation Process - Non-EPA organizations shall request the delegation of QAPP approval authority from the RQAM. The RQAM will notify the Project Officer of the Programmatic Division or Office, who will coordinate the Programmatic Criteria assessment with his/her Management. If the delegation is deemed acceptable by the RQAM and Management, the RQAM will respond to the requesting organization, relaying any limitations or exceptions and requiring that the process be defined acceptably in the organization's QMP. The correspondence giving the approval shall be coordinated through the Project Officer and Deputy Division Director of the Programmatic Division or Office and other areas designated by any involved in the concurrence process. The correspondence to the requesting organization may grant approval of the delegation and be used by the requesting organization as an interim change to their QMP, until the next routine revision. The delegated QAPPs will be submitted to the Project Officer for tracking (see Section 1.11).

1.17 Information Quality Guidelines

EPA's **Information Quality Guidelines** (IQGs) contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates. They are interrelated to the Regional Quality System for assuring the quality of EPA's data products and information. "Information" generally includes any communication or representation of knowledge, position or policy such as facts or data in any medium or form. This encompasses "preliminary" information that EPA has endorsed or adopted and includes conclusions or facts drawn from or based upon other existing information. This QMP incorporates by reference all

definitions, principles, policies and **procedures** found in EPA's IQGs (URL is https://www.epa.gov/quality/epa-information-quality-guidelines).

1.17.1 Implementation Policy and Procedures

Region 6 will comply fully with EPA's IQGs and where needed will establish policies and procedures for complying with these guidelines. Emphasis will be on using existing Regional processes and procedures wherever possible to comply with the requirements of the IQGs. The review process is intended to ensure the quality of the Region's **information disseminations** and is incorporated into the QAPP review processes for Programmatic Divisions and Offices. The Region 6 IQG Coordinator assumes responsibility for coordination of the IQG process in Region 6 with the OMS/EI. The IQG Coordinator is supported by the Office of Regional Counsel and the applicable Division's staff with responsibility for the particular programmatic area(s) involved in any IQG Requests for Correction (RFC) and/or Requests for Reconsideration (RFR).

1.17.2 Request for Correction (RFC)

The IQGs allow for affected persons to request correction of information if that information does not comply with EPA or OMB IQGs. The OMS/EI will receive these RFCs and forward them to the Region 6 IQG Coordinator when the information in question belongs to or involves Region 6. Upon receipt of the RFC from the OMS/EI, the IQG Coordinator will notify the Office of Regional Counsel and the responsible Programmatic Division(s) or Office(s).

1.17.3 Request for Reconsideration (RFR)

The IQGs allow for affected persons to request a reconsideration of EPA's decision on an RFC of information if they are dissatisfied with the decision. The OMS/EI will receive these RFRs and forward them to the Region 6 IQG Coordinator when the information in question belongs to or involves Region 6. Upon receipt of the RFR from the OMS/EI, the IQG Coordinator will notify the Office of Regional Counsel and the responsible Programmatic Division(s) or Office.

1.18 Pre-dissemination Reviews

EPA's IQGs also addresses Pre-Dissemination Reviews. For data related projects performed by or for Region 6 that require a QAPP, the process of QAPP approval, as defined in this QMP, will address the Pre-dissemination review process. Information acquired without a QAPP developed by or for Region 6 shall undergo Pre-Dissemination Review prior to dissemination. More information concerning Pre-Dissemination Review can be found at: https://www.epa.gov/quality/epa-information-quality-guidelines

2. QUALITY SYSTEM COMPONENTS

The Region 6 quality system utilizes a centralized QA organization, and it relies on an RQAM, QA Staff and trained and knowledgeable individuals in the various Programmatic Divisions and Offices to accomplish the QA functions. In this quality system, each level of the organization has a responsibility to provide products and services of the quality needed and specified by its customers. Effective oversight of the quality process becomes the responsibility of the customer to assure quality is received from his/her **suppliers**.

The RQAM assumes the lead role for preparation of the Region 6 QMP and its periodic updates. This is accomplished through formal meetings of the Region 6 **QA Forum** (see section 10) and the RQAM and their joint assessment of all elements of the QMP. In addition, the QA Staff may use the assessments defined in Section 9 to evaluate the quality performance criteria identified in this QMP.

2.1 Division QA Functions

Each Region 6 Division and Office Director or delegated shall be responsible for the following QA activities within his/her respective Division or Office in accordance with the Region 6 August 2017 QA MOU and this QMP:

2.1.1 Implementation of this QMP for Division operations involving environmental data operations, including the Division's internal and external (both grants or cooperative agreements and contracted) projects;

2.1.2 Review and approval of QAPPs for which an approved QMP exists;

2.1.3 Provide approval status of QAPPs to the RQAM or delegated personnel;

2.1.4 Concurrence and submission to the RQAM requests for QAPP exemptions;

2.1.5 Ensuring information is accurate in the QTRAK database for the Division or Office;

2.1.6 Providing routine technical guidance to customers on the development and submittal of QAPPs;

2.1.7 Providing technical assistance to customers both at and outside EPA

2.1.8 Referring applicable technical guidance requests from customers to the RQAM;

2.1.9 Maintenance or oversight of a file system that contains an original copy, or electronic equivalent of an original copy of all his/her organization's valid QAPPs;

2.1.10 Participation as a Team Member in MSRs or QSAs and other **audit**/review functions as described in Section 9;

2.1.11 Perform laboratory assessments of state, commercial, tribal and/or other government laboratories as required by Safe Drinking Water Act (SDWA), Clean Water Act (CWA) and Contract Laboratories Program (CLP);

2.1.12 Perform QA assessment activities, including **technical systems audits** (TSA), data quality audits and performance audits for the Clean Air Act (CAA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), CFR and other programmatic requirements;

2.1.13 Provide assistance to Project Officers as described in Chapter 46 of the EPAAG and participate as a member of the Technical Evaluation Panel as directed by the COR or CO;

2.1.14 Assistance in determining QA needs of his/her respective Division and any State, Municipality, University, Nonprofit Organization or Tribal grantee or cooperative agreement holder under the Division's purview;

2.1.15 Implementation of Regional QA policy at the Division or Office Level;

2.1.16 Serve and/or support the QA Forum through their members and to exercise their role in appointing, reappointing, extending or removing their members as outlined in Section 10.2 and

2.1.17 Submittal of requested QAPP expiration date extensions to RQAM.

2.2 Data Quality Objectives Process

The Data Quality Objectives (DQO) Process is an essential tool to be used in planning all environmental data operations. DQOs shall be developed following all applicable OMS/EI/OEIP/EQMD guidance, as defined in the current Guidance on Systematic Planning using the Data Quality Objectives Process, (EPA QA/G-4). All QMPs shall require that DQOs or equivalent **systematic planning process** be an essential element of all QAPPs and contain a mechanism for assuring compliance. This is applicable to activities delegated to State, Municipal, University, Nonprofit Organization, Tribal grantee, cooperative agreement holder or conducted by a contractor. For all enforcement related projects, the appropriate legal counsel shall be involved in the DQO development process to assure that evidentiary needs are met. The purpose of any systematic planning process is to apply the **graded approach** to attempt to assure that the level of controls applied to proposed work is assessed according to the intended use of the results and the degree of confidence needed in the quality of the results.

2.3 QAPPs

EPA Order CIO 2105.0 requires that every project involving an environmental data operation or the use of **secondary data** (**historical data**) shall have a written QAPP approved prior to initiation of environmental data operations.

A QAPP presents, in specific terms, the policies, organization, objectives, functional activities, QA, and QC activities designed to achieve the DQO's of a particular project or continuing operation. The typical **characteristics** of a good QAPP are:

- requirements for management and technical audits and a process for correction of deficiencies,
- requirements for documenting sampling **design**, sampling procedures and data analysis, and
- the definition of specific QA and QC activities.

OMS/EI/OEIP/EQMD is responsible for guidance on format and areas of coverage for QAPPs. QMPs that are used in the collection of environmental data by all who are funded to do so for EPA will delineate specific approval and concurrence requirements that comply with this QMP and Chapter 5 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0. In addition, all contracts have to meet the QA requirements of the EPA Acquisition Regulation (EPAAR), which is outlined in Title 48 CFR Part 46. The RQAM does not use any contract services to perform QA related activities. The Programmatic Divisions and Offices that utilize contract services follow the process and QA requirements described in Section 4.2.

Each QAPP must cite the associated QMP(s) and its effective date. No QAPP can be approved without an approved QMP, as the QMP is essential for defining the criteria of a QAPP. The QMP and QAPP can both be approved at the same time (i.e., a combined QMP/QAPP) or separate documents on the same day. Implementation of QAPPs shall be evaluated by each respective Division and the RQAM will maintain oversight through MSRs, QSAs, Audits and other means.

The Project Officer or COR may provide guidance in the development of QAPPs as dictated by the approved work plan, work assignment or task order. When necessary, the appropriate senior Project Officer within their Programmatic Division or Office, along with technical assistance from the appropriate section(s), will provide guidance for developing QAPPs in the planning phase of a project. Workplans provisions shall stipulate that for those QAPPs that exceeded the three-year life, the recipient may proceed with work without interruption provided that the revised QAPP has been submitted to the Project Officer within their division for approval 60 calendar days prior to the expiration date, if the expiration date has been extended by the Project Officer and delegated approving official.

Upon receipt of a QAPP, the Project Officer or COR will (as appropriate) distribute the QAPP for **technical review**. Written comments and/or comments from the technical reviewer(s) will be provided by the Project Officer or COR to the submitting organization within 30 calendar days of receipt. The Project Officer or COR will prepare an approval letter or memorandum regarding the QAPP. The QAPP is signed by the Project Officer or COR. The approval letter along with the copies of the signature page(s) is sent to the submitting organization. If

applicable, the Programmatic Division or Office will document the QAPP approval in the Programmatic Division or Office tracking/reporting system (i.e. Water Division database BRATS). The Project Officers and CORs for grants, cooperative agreements and interagency agreements will send an email to the Region 6 Laboratory Services and Applied Science Division for the purpose of recording the QAPP approval in the Region 6 QTRAK database (see Sections 1.11 and 6.3). The provisions of the existing approved QAPP shall remain in force until final approval of the revised QAPP. Further details of the external QAPP review and approval process are documented in Section 5.1.

2.4 Internal (In-House) Projects

The RQAM shall provide guidance in the development of QMPs and QAPPs during the planning phase of each monitoring activity. The Region 6 QMP and QAPPs shall adhere to the **standards** outlined by the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0, Chapters 3 and 5 respectively.

2.5 External Projects - Grants, Contracts and Cooperative Agreements

This category includes those projects conducted under Agency financial assistance programs, such as grants, cooperative agreements, interagency agreements, contracts, etc. QA requirements for the different types of projects and contracted services are described in Title 2 CFR Part 1500.11, Title 40 CFR Part 35 and Title 48 CFR Part 46, EPAAG and EPA Order 1900.2. The QA functions required by these documents are delegated to each Programmatic Division or Office and the Project Officers. Section 8 describes the implementation process. The QAPPs required of awardees or contractors shall be developed consistent with EPA guidance and regulations and this QMP. The project recipient can begin data collection once the QAPP is approved. The grant recipient should ensure that all appropriate staff members performing work covered by the scope of the QAPP are notified of changes of the QAPP so that they are informed of the current requirements. This notification should include any contractors or subcontractors performing the work to assure compliance with these approval and revision requirements.

2.6 QA Status Report Requirements - QAPPs

For data collection projects expected or planned to be completed within eighteen months, a single QA status (final) report is required at the conclusion of the project. For projects expected or planned to continue longer than eighteen months, an interim QA status report is required every twelve months after data collection begins and at the conclusion of the project. These reports shall be submitted to the responsible Region 6 program office staff. The QA report on each project should be a separately identified Status Report (both interim and final) addressing as a minimum the following areas:

- QA management (any changes);
- Status of completion of the QAPP;
- Measures of data quality from the project;
- Significant quality problems, accomplishments, and status of corrective actions;
- Results of QA performance audits;
- Results of QA systems audits;
- Assessment of data quality in terms of precision, **accuracy**, **completeness**, **representativeness** and **comparability**; and
- QA related training.

This process consists of the grantee providing an update to their Project Officer via an email.

2.7 Standard Operating Procedures

SOPs may be developed and incorporated into QMPs, QAPPs or QA Manuals by reference and/or attachment. Use of SOPs is encouraged both as a **method** to reduce variation and to reduce costs, when a similar method or process is utilized in a number of projects or programs. SOPs should follow the Guidance for Preparing Standard Operating Procedures (QA/G-6).

Internal

Region 6 SOPs are for internal office use only and are subjected to internal **peer review** and approval by those delegated. Each Region 6 SOP will be reviewed, updated and/or revalidated to meet the requirements identified in Section 1.5. The Programmatic Division or Office maintains copies of program specific EPA SOPs developed internally and/or by national program offices for reference purposes.

Region 6 has implemented the QAFAP requirements and established nine SOPs to address how the Region implements the field guidelines. The Region 6 QAFAP SOPs may also be supplemented with program specific procedure documents to provide additional detail on program activities not included. Program specific procedures, guidelines and checklists should also be controlled in a manner consistent with this section. Contact the Regional Field Quality Manager for site access and the Region 6 QAFAP SOPs.

The EPA Region 6 Laboratory Services and Applied Science Division Laboratory (R6 Lab) QA Manual provides the process for SOP review, approval and the management of the SOPs in the Laboratory Information Management System.

External

Each external QMP defines the method by which SOPs will be developed, reviewed and approved. At a minimum, all external SOPs will be reviewed, updated and/or revalidated on a periodic basis as identified in the QMP.

2.8 Dispute Resolution Process

While recognizing that all Region 6 staff and managers have specific data quality requirements and everyone should work toward a common goal, there are times when differences of opinion do arise that can create conflict between the various organizational elements. If there are issues that do arise regarding the fulfillment of quality system requirements of this QMP, EPA Policy or the CFR, then the applicable process discussed below will be followed to resolve the issue. The Dispute Resolution Process is an EPA only and internal activity.

2.8.1 Interdivisional Dispute Resolution Process

If there are data quality related issues between the organizational elements of the Divisions, the RQAM shall be notified by the Programmatic Division or Office of the issue. If the issue is over interpretation of Regional QA policy, the RQAM shall resolve the issue. If the issue is not within the purview of the RQAM to resolve, then the RQAM, in conjunction with appropriate managers from the involved Divisions, shall work together to resolve the issue. If the matter cannot be satisfactorily resolved at this level, the RQAM shall involve the Division Director for Laboratory Services and Applied Science Division, who will seek resolution from his/her peers. Failing to reach resolution at this level, the Division Director for Laboratory Services and Applied Science shall seek resolution from the RA or Deputy RA.

2.8.2 Intra-Divisional Dispute Resolution Process - Programmatic Division or Office

If there are data quality related issues within the organizational elements of a Programmatic Division or Office, the RQAM shall be notified by the appropriate manager of the issue. If the issue is over interpretation of Regional QA policy, the RQAM shall resolve the issue. If the issue is not within the purview of the RQAM to resolve, then the RQAM, in conjunction with appropriate managers from the involved organizational elements, shall work together to resolve the issue. If the matter cannot be satisfactorily resolved at this level, the appropriate Division Director shall resolve the issue with the concurrence of the RQAM. If concurrence is not granted, the RQAM shall involve the Division Director for the Laboratory Services and Applied Science Division, who will seek resolution from his/her peers. Failing to reach resolution at this level, the Division Director for the Laboratory Services and Applied Science Division shall seek resolution from the RA or Deputy RA.

2.8.3 Intra-Divisional Dispute Resolution Process – Laboratory Services and Applied Science Division

If there are data quality related issues between the RQAM and an organizational element of the Laboratory Services and Applied Science Division, the Division

Director for Laboratory Services and Applied Science Division shall select a neutral arbitrator to attempt to allow the involved parties to resolve the issue. If the matter cannot be satisfactorily resolved at this level, the Division Director for Laboratory Services and Applied Science Division shall recuse him/herself and seek resolution from the RA or Deputy RA.

3. PERSONNEL QUALIFICATIONS AND TRAINING

3.1 QA Staff Qualifications

The QA Staff shall fulfill the educational, work experience and training requirements for their positions, as outlined by the Office of Personnel Management in their position descriptions. The QA Staff will attend meetings and take courses that enhance their knowledge of QA, the technical aspects of the programs they consult and environmental analytical methodology, as time and funds permit. It is imperative that all QA personnel continue to be informed of changes in the Agency's Quality System and/or polices and of developments or changes in National, International or Industry Standards.

3.2 QA Training and Certification

The following courses are offered by Region 6:

- Quality Project and Program Management
- QA Refresher (EPA only)
- QAFAP Trainings (EPA only)

The Quality Project and Program Management course is intended for those who are involved with any aspect of the QA program, either at EPA, or a State, Municipal, University, Nonprofit Organization or Tribal Organization. It is primarily for those who write, review or approve QMPs and/or QAPPs. QA Refresher course is a recap of the Region's QA policies and procedures and is intended for Region 6 staff members who have not taken the basic QA course within the previous three years. Prior to 2011 there were three courses that together were considered equivalent to the Quality Project and Program Management course. Titles of those courses were: Orientation to QA Management; Data Quality Objectives; and QMP/QAPP Seminar. The Quality Project and Management course provides an overview of assessments described in Section 9 and includes real life examples. The QAFAP Trainings are intended for Region 6 field staff who are involved with field activity procedures as defined in EPA CIO 2105-P-02.0 and Region 6 QAFAP SOPs. Details regarding the identification of personnel and training can be found in the Region 6 QAFAP SOP for Personnel and Training (R6PROC-001), current version.

Courses are primarily for EPA employees, and with adequate need and availability of resources, State, Tribal or other cooperative agreement holder's employees and contractor personnel may also take QA courses. Instruction given by the programs may be substituted for these courses if they are approved by the RQAM. A list of the courses and the dates they will be taught will be forwarded to the RQAM annually and included in the Quality Assurance Annual Report and Work Plan (QAARWP) to OMS/EI/OEIP/EQMD. Additional classes will be scheduled if the

demand exists. The QAFAP Trainings are internal for EPA Region 6 and primarily for those who perform the field work. The courses offered by EPA Region 6 are available for management.

All QA Staff shall attend Quality Project and Program Management course at the earliest opportunity, as well as other OMS/EI/OEIP/EQMD offered courses (webinars). Region 6 shall present training to meet mission needs, and instructors are to be QA Staff that have taken the particular course they are to present or be a recognized subject matter expert before they may teach a particular course.

The courses will be reviewed on an annual basis and, in response to course critiques, the necessary improvements will be made to the courses and teaching techniques. In addition to the Basic Project Officer training, each Project Officer that prepares, reviews or approves QMPs and/or QAPPs shall have completed the Quality Project and Program Management course above, prior to reviewing QA planning documents. Project Officers are encouraged to take other courses as they are offered. Individuals that approve QAPPs and sign the QA Certification Form (see Section 1.12), shall be certified by the Region 6 RQAM. Successful completion of the Quality Project and Program Management course will be the initial requirement for certification for individuals in each Division that prepare and/or approve QAPPs and sign the QA Certification Form (see Section 1.12). The certification is good for a period of 3 years and can be extended by the RQAM. Before the certification expires, the individual will receive notification of the pending expiration of his/her certification. To renew this certification for an additional three years, the individual shall successfully complete the QA Refresher Course. All individuals that are writing or reviewing QMPs or QAPPs shall complete the Quality Project and Program Management course. Exceptions from the above certification requirements may be granted by the RQAM upon presentation of objective evidence of similar and equivalent training or experience in the QA field.

A list of properly trained and certified individuals will be maintained by the RQAM. All of the courses will be offered to the State, Municipal, Nonprofit Organization and Tribal Grantees or cooperative agreement holders, if resources are available. The individuals writing Region 6 QMPs are required to take the Quality Project and Program Management course. Prerequisites are as follows:

- Quality Project and Program Management - No prerequisites, open to anyone;
- QA Refresher Course - Prerequisite - Completion of the Quality Project and Program Management Course, open to EPA personnel;
- QAFAP Trainings - No prerequisites, open to EPA personnel.

These courses were designed and have been used to earn continuing education credits or units. These continuing education credits are used to satisfy the training requirements for professional certifications and requirements for CO and COR.

4. PROCUREMENT OF ITEMS AND SERVICES

The goal of Region 6 is to provide goods or services that comply with predetermined levels of quality and meet the needs and expectations of the customer. A suitable method for accurately translating the customer's needs and expectations to the supplier is a contractual document or a grant or cooperative agreement document that clearly states those needs and expectations to both customer and supplier.

4.1 Applicability

These requirements apply only to those Region 6 procurement actions (as opposed to those originating at EPA Headquarters or other non-Region 6 elements) or suppliers who provide services or **items** that directly affect the quality of results or products (e.g., analytical laboratory services, sample collection or sampling plan preparation) for environmental programs.

4.2 QA Requirements

All Programmatic Divisions and Offices and programs that utilize contracted services or products that eventually yield environmental data will specify or require the description of the QA requirements in a QMP by the provider or prospective provider of the services or products.

This shall be accomplished by meeting the administrative and QA requirements as defined in the current versions of:

- the Federal Acquisition Regulations (FAR), Part 13
- the EPAAG

The QMP(s) will be reviewed as described in Sections 1.7 and 1.8.

5. DOCUMENTS AND RECORDS

QA related documents and records are identified by the QA Staff and Project Officers. It is the responsibility of the individual, Programmatic Division or Office or program identifying the quality related documents and records to manage or control in accordance with guidance and policies identified in this QMP. All QAPPs submitted to Region 6 for approval will be reviewed by the program office administering the work and will be approved or disapproved as stipulated in Section 2.3 of this QMP. Other QA Documents or records including but not limited to the QA Manual or SOPs are maintained and tracked by the program as specified by the document and/or Programmatic Division or Office to meet the requirements in this QMP.

5.1 Documentation and Procedure for Review of Quality Plans

The process used to review quality plans below is provided as specific guidance for QMPs and as general guidance for QAPPs.

5.1.1 QMP Review and Approval Process:

- EPA Requirements for Quality Management Plans (EPA QA/R-2) will be used as the standard for reviewing submitted plans from external sources, and Chapter 3 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0, will be used for internal QMPs.
- All QMPs submitted to the Region will be reviewed for final approved or disapproved status by the RQAM (or delegated), who is the final approval authority for QMPs.
- QMPs received by program office staff shall be expeditiously forwarded to the RQAM to allow for a timely review, along with any appropriate comments.
- Any QMP that is disapproved by the RQAM will be returned to the submitter for further action along with an explanation for the disapproval (please refer to Section 1.8).
- Approved QMPs will be filed and maintained by the RQAM or delegated within the filing and QTRAK systems or entered in the Programmatic Division or Office tracking/reporting system if applicable.
- The Electronic Signature Policy in addition to the Records Management Policy and Guidance (see Section 5.3, Records Maintenance) shall be followed to determine these requirements.

5.1.2 External QAPP Review and Approval Process:

- Each program will review or approve QAPPs submitted to their Programmatic Division or Office. This document will address the QA

requirements that assure a level of consistency within Region 6 in accordance with the graded approach.

- The review of external QAPPs will be conducted using EPA Requirements for QAPPs (EPA QA/R-5) and the G-5 checklist, current version or replacement document as detailed at the Agency-wide Quality System Documents (URL is https://www.epa.gov/quality/agency-wide-quality-system-documents) as a standard and Chapter 5 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0, will be used for internal QAPPs.
- Additional guidance documents regarding QAPPs both in general and for specific types of QAPPs are also available at the URL https://www.epa.gov/quality/epa-quality-management-tools-projects#tab-2
- The applicable approved QMP should be used by the QAPP reviewer for the program and organizational process specific guidance.
- Approved QAPPs will be maintained in the project files of the approving programmatic office.
- The RQAM will have unrestricted access to all QAPPs. QAPPs can be approved after the applicable QMP has been approved or at the same time (i.e., a combined QMP/QAPP).
- Each QAPP shall cite the QMP that it falls under either in the QAPP or within the QTRAK system.
- The QAPP with original signatures is received in the Region and date stamped to document date of receipt.
- The Project Officer will request a QTRAK number for the QAPP from the Laboratory Services and Applied Science Division QTRAK Administrator. See Section 1.11.
- If applicable, the relevant information will be entered in the Programmatic Division or Office tracking/reporting system (i.e., Water Division BRATS database).
- The Project Officer will review the QAPP to determine if all required elements have been included. If the QAPP is complete, then the Project Officer will route the QAPP to the appropriate section for technical review.
- The Project Officer will send a letter or email to the agency to acknowledge receipt of the QAPP, provide the QTRAK number and indicate when a response will be provided.
- The reviewer will assure that the preparer of the QAPP has addressed all appropriate programmatic and legal requirements for the generation and management of the data and information.
- These requirements include, but are not limited to, the generation, use, and management of sensitive information (including Confidential

Business Information and the Freedom of Information Act).

- The Electronic Signature Policy in addition to the Records Management Policy and Guidance (see Section 5.3, Records Maintenance) shall be followed to determine these requirements.
- Region 6 must provide a written approval of the QAPP within 30 calendar days of receiving the QAPP. If Region 6 can't approve the QAPP, then the Project Officer must provide notification and/or comments to the grantee within 30 calendar days as well (the QAPP can also be declined).
- If Region 6 has comments, an email or letter providing the comments should include the requirement for a revised QAPP in hard copy with new signatures and include the due date for the grant recipient to submit the revised QAPP.
- If the QAPP can be approved, then the Project Officer will prepare a formal hard copy letter to approve the QAPP. The letter should include the approval and expiration dates, the QTRAK number, a reminder that the QAPP will need to be resubmitted at least 60 calendar days prior to expiration and a reminder of the criteria that will trigger a requirement to revise the QAPP.
- Once the QAPP is approved the Project Officer or COR notifies Laboratory Services and Applied Science Division to record the approval in the QTRAK system.
- If applicable, the relevant information will be entered in the Programmatic Division or Office tracking/reporting system (i.e., Water Division BRATS database).
- After approval, the revised QAPP shall supersede all previously approved documents, unless otherwise stated.

5.1.3 Internal QAPP Review and Approval Process

- QAPPs are required for direct or secondary environmental measurements used in decision-making by the Programmatic Divison or Office.
- The preparation of the QAPPs will be by divisional staff or subject matter experts.
- The QAPP is signed by the Project Officer or the COR of the appropriate section.
- The Electronic Signature Policy in addition to the Records Management Policy and Guidance (see Section 5.3, Records Maintenance) shall be followed to determine these requirements.
- Upon approval, the appropriate staff will provide an email to the Laboratory Services and Applied Science Division for the purpose of recording the QAPP approval in the QTRAK database.

- If applicable, the relevant information will be entered in the Programmatic Division or Office tracking/reporting system.
- After approval, the revised QAPP shall supersede all previously approved documents, unless otherwise stated.

5.2. Tracking of Quality Plans

A status record of all QMPs and QAPPs will be maintained on the Region's QTRAK Database (see Section 6, Use of Computer Hardware and Software). The RQAM, delegated and the Project Officers will monitor QTRAK to ensure that all QMPs and QAPPs are current. Automatic responses will be sent out from QTRAK notifying Project Officers and reviewers that quality plans will expire within 60 calendar days. Should one of these documents become outdated, the RQAM or the delegated shall determine the status of the plan, and initiate appropriate action, in addition inform the appropriate Project Officer of the QTRAK number for QAPPs or applicable QMP upon request.

5.3. Record Maintenance

The responsibility for e-signature in addition to Regional Records Management is within the Mission Support Division in the IT & Operations Management Branch, and this branch is the organizational location of the Regional Records Liaison. All QA documents or copies thereof, which are sent to, generated by and/or sent from the RQAM, Project Officers or QA Coordinator will be filed according to the appropriate e-signature, Records Management Policy and Guidance as well as Statutes and Laws. This can be found at the EPA Records website by using the URL http://www.epa.gov/records/.

With regards to QMPs and QAPPs, status records will be maintained on the Region's QTRAK Database and/or each Programmatic Office or Division. The RQAM, QTRAK Administrator and the Project Officers will monitor QTRAK to ensure that all QMPs and QAPPs are current. The RQAM is responsible to maintain the historical QMPs and work with the Records Management for archiving the documents. Information regarding retention and disposition schedules are also available at the URL http://www.epa.gov/records/.

6. COMPUTER HARDWARE AND SOFTWARE

6.1. Policy

It is a Region 6 QA management objective that data collected, analyzed, processed and/or maintained on all **Information Technology** (IT) systems, in support of environmental studies, be accurate and of sufficient integrity to support effective environmental management.

In order to ensure the effective and efficient use of the Regional IT systems, including hardware and software system design, development, implementation and maintenance, Region 6 will follow the EPA Information Resource Management (IRM) Policies developed by the OMS/EI. These EPA policies can be accessed at its index URL, https://www.epa.gov/irmpoli8.

6.2 Computer Hardware and Software Requirements

EPA's OMS/EI and the Office of Information Technology Operations (OITO) are responsible for managing the hardware, software and communications components that form the foundation of the Agency's information technology. OITO is responsible for the implementation and management of a secure IT infrastructure and IT solutions in support of EPA's Mission with which the Region must conform. Region 6 managers and staff will observe all hardware and software standards as detailed in the OMS/EI Directives System at URL https://www.epa.gov/irmpoli8/current-information-directives. This directive system is applicable to the personal computer (PC) platform, local area network and server platforms, cloud platforms, open systems platforms, Agency electronic mail service, IBM Compatible Mainframe Platform and Supercomputer Platform.

Specifically, OITO will be responsible for assessing significant changes in the Agency's hardware and software policy to determine any impact on the Region. In the event changes are required, management from the Region 6 IT Services Section, along with OITO, will work with regional management to plan and implement appropriate modifications. When software/hardware changes are necessary, the following must be followed and upheld with IRM authority/approval:

- All hardware and software shall meet EPA's IRM Hardware and Software Standards of the OMS/EI.
- All software systems shall be developed and designed according to the EPA System and Development Guidance of the OMS/EI.
- All software systems shall be operated and maintained according to EPA Operation and Maintenance Manual from the OMS/EI.
- For integrity of computer-resident data in stand-alone PC systems, the laboratories or offices, which use systems for environmental effects studies, shall follow the EPA Good Automated Laboratory Practices guidelines from the OMS/EI.

6.3 QTRAK

QTRAK is a computer program that contains database information on QMPs and QAPPs for the Program Managers, Project Officers and the QA Staff for tracking, planning and assessment of the status of Regional QMPs and the associated QAPPs. Contact the QTRAK Administrator for site access.

QTRAK has been developed as an Oracle database. The QTRAK database contains a complete listing of the Region 6 QMPs and their associated QAPPs required by the Agency, current status of the plans, name of the agencies involved, approval date of the plans, names of the Project Officer and the reviewer of the plans. QTRAK also contains the QA Certification Forms (see Appendix C). QTRAK is available to all Region 6 personnel for read access only. Data can be entered into the system only by the RQAM or by the QTRAK system administrators. Each QA document in QTRAK is issued a unique QTRAK number (See Section 1.11).

6.4 Data Management

To take full advantage of the Region's growing technological and data resources, there needs to be an increased emphasis on improving compatibility of data among different systems. For consistent definition of data and to facilitate cross-media use of data, all data produced or collected by the computers shall be managed as specified in the Agency IRM Policy Manual. The Agency is in the process of developing Agency-wide **data standards**, in the Agency Catalog of Data Policies and Standards. This catalog will summarize Federal data policies and standards which are the definitive list of data standards that Agency personnel and contractors shall meet when developing **information systems**.

Region 6's electronic files are stored in two locations: the region's local area network (LAN) and Microsoft Cloud (e.g. SharePoint and/or OneDrive). The LAN is required to be backed-up incrementally Monday through Thursday, and fully backed-up starting on Friday evenings. One backup is conducted remotely from the Office of Research and Development computer center and another locally from Region 6's computer center. Backups are stored offsite in a fire-proof media safe, located at Region 6's Addison Facility. The Region 6 LAN data backup procedures are defined in Region 6 LAN (R6LAN) Information System Contingence Plan, (ISCP) dated February 8, 2018. Contact the Region 6 Information Security Officer for site access.

6.5 Information Security

It is important that the Region's information resources are protected from potential loss and misuse from a variety of accidental and deliberate causes which can take the form of destruction, disclosure, alteration, delay or undesired manipulation.

For a comprehensive, Region-wide security program to safeguard the Region's information

resources, all information resources shall be safeguarded as specified in the Agency's Information Security Policy at URL https://www.epa.gov/irmpoli8/information-security-policy.

6.6 Documents

For proper implementation and maintenance of the IT system, the appropriate Divisions shall document the following in SOPs:

6.6.1 A written description of the computer system(s) hardware and written operating procedures for routine maintenance operations;

6.6.2 A written document which contains detailed description of the software in use, including the listing of all algorithms or formulas used for data generation, processing and assessment, clear guidelines for data acceptance criteria, criteria for **data validation**/invalidation, data deletion/addition, and data correction; and

6.6.3 SOPs which describe the routine operation, maintenance and testing, to ensure that both the hardware and software is accurately performing the intended functions. These documents shall be readily available in the areas where these procedures will be performed. Published literature or vendor documentation may be used as a supplement to software documentation if properly referenced therein. All deviations from the operational instructions for data collection systems shall be authorized by the delegated. Changes in any part of the operating procedures shall be properly authorized, reviewed and accepted in writing by the delegated.

6.7 Personnel

Personnel involved in computer data collection systems, hardware and software shall:

6.7.1 have adequate education, training and experience to perform the assigned system functions;

6.7.2 have a current summary of their training, experience and job description, including information relevant to system design and operation maintained at the facility and

6.7.3 be of sufficient number for timely and proper conduct of the study, including timely and proper operation of the automated data collection system(s).

7. PLANNING

In the Region 6 QA system, the RQAM is not involved in the QAPP/DQO planning process or **data quality assessment**, except in the capacity of meetings, training, MSRs, QSAs and other assessments. The planning process used for projects involving **environmental measurement** are outlined for the Region 6 Programmatic Divisions and Offices. The RQAM utilizes a work plan showing planned actions on a fiscal year basis as his/her primary planning document (discussed further in paragraph 8.3).

For the collection of environmental information and data, Region 6 endorses the use of DQOs as the primary systematic planning tool. DQOs and the DQO Process are described in the Guidance on Systematic Planning using the Data Quality Objectives Process (QA/G4) available at the URLhttps://www.epa.gov/sites/production/files/documents/guidance_systematic_planning_dqo_process.pdf. The DQO process has been a very effective tool when used with the graded approach.

The seven steps of the DQO process allows the project planner to focus on the goals of the project and the quality needed to achieve those goals. This process includes the identification of the project schedule and milestones that are used to ensure that the schedule is met. The needed resources are identified with a focus on the limitations that resources impose on projects. Also, the process will identify how, when, and where the data will be obtained. Data can be obtained as part of this project (primary data) or can come from existing sources (**secondary data**). The project planner can then identify any constraints on data collection and limitations on the use of the data.

The primary aim of any systematic planning process (including the DQO process) is the identification of the type, quantity, and quality of the data to be collected that will support the objectives of the project. Once the type and quantity of the data are determined, the project planner can specify the performance criteria needed for measuring the quality. These performance criteria are used to identify the specific QA and QC activities that will be used to access the quality performance criteria. These QA and QC activities include such activities as **data verification** and **validation** and the limitations on project specific **data quality indicators**.

The DQO process will also guide the planner in the determination of how the acquired data will be analyzed, evaluated, and assessed against the intended use of the data and the quality performance criteria.

7.1 Routine Planning Process

During the 4th quarter of each fiscal year, the QA Forum (please see section 10) shall make recommendations to the RQAM based on its customer feedback. Since the QA Forum will meet

with the RQAM on an as needed basis, to provide timely customer feedback, these customer needs will be obtained routinely.

7.2 Urgent Customer Needs

On a short-term basis, if the QA Forum or any customer becomes aware of urgent QA needs not previously planned for, they will recommend to the RQAM and Division Director for Laboratory Services and Applied Science Division that this urgent need be addressed.

7.3 Resource Allocation

The resources necessary to implement the QA program are described in the August 2017 QA MOU (Appendix B).The Laboratory Services and Applied Science Division commits to travel funds for the RQAM to conduct essential centralized functions such as external MSRs, QA training and QA professional development. The Division also commits to travel funds for the QA Staff to perform required QA activities such as audits, If the QA Staff are requested to provide assistance to a Programmatic Division, supported office or their customers, any travel funds involved are the responsibility of the applicable Division or Office.

In order to accomplish the Regional QA Program goals, each Programmatic Division or Office will provide travel funding for the conduct of QA training and to perform MSRs or QSAs. Each Programmatic Division or Office will provide staff resources for the conduct of QA training and to perform MSRs and QSAs. The RQAM will attempt to assure the burden of QA related travel funds and the use of Programmatic staff are equitable among the Programmatic Divisions and Offices for the entire QA Program.

8. IMPLEMENTATION OF WORK PROCESSES

Environmental data must be of known and acceptable quality. Therefore, environmental data operations must be implemented in accordance with procedures outlined in approved QMPs and QAPPs. Any deviations from these must have received approval from Region 6.

8.1 Programmatic Divisions and Offices

The QMP of each grantee or contractor addresses the process for implementing environmental data operations according to the approved planning documents. Work performed under grantee and contractor QMPs and QAPPs are evaluated by the appropriate program staff through status reports, periodic QA report, periodic site visits or assessments (See Section 9). If applicable, SOPs or program guidance documents are utilized for routine or standardized activities.

Specific activities that will be undertaken to ensure the quality of environmental data in the Programmatic Divisions or Offices or programs are identified in individual QAPPs. These requirements are also identified in agreements between EPA and the recipients of financial assistance including work plans. The Programmatic Division or Office reviews all plans according to EPA, national and or regional guidelines. The level of management oversight and review necessary to adequately ensure that work is being performed according to the plan will commensurate with the importance of the project and the intended use of the project results as determined by the Programmatic Division or Office or program.

8.2 Tracking of Implementation

Routine performance is measured against established technical and quality specifications by the Programmatic Division or Office or program. Program guidance, project work plans, QAPPs or SOPs are used as a guideline for measuring performance. Performance is measured during assessments as described in Section 9.

The QMPs and QAPPs preparation, submittal, review, approval and issuance follow the procedures outlined in this QMP. All of these activities will be tracked by the QA Staff and reported to Region 6 senior management. Significant slippage of milestones or inability to accomplish planned activities will be addressed in the QA Forum's update to the RQAM.

8.3 Quality Assurance Annual Report and Work Plan

The QAARWP is performed as resources allow and as requested from OMS/EI/OEIP/EQMD. The QAARWP has two parts, the annual report of accomplishments for the previous fiscal year and the proposed work plan for the new fiscal year. The OMS/EI will supply the format for the QAARWP each year, normally in the last quarter of the fiscal year, to all EPA Organizations. The

preparation and submission process is generally defined in Chapter 4 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0. This report and plan will be developed by each Division and Office, collaboratively by the RQAM and the QA Forum. The call letter for the QAARWP usually is issued in mid-September with submission required (under the RA's signature) by the end of October. The Laboratory Services and Applied Science Division will be the lead in preparing the QAARWP and the Programmatic Divisions and Offices agree to provide input to the plan through their QA Forum members to the Division in a timely manner. Prior to final submission of the QAARWP to the RA for signature, the proposed QAARWP will be submitted to the QA Forum and individual Directors for concurrence. Last submission of request was 2016.

9. ASSESSMENT AND RESPONSE

In order to ensure that QA plans are being implemented and are adequate for their intended purpose, technical and managerial assessments at both the program level and the project level are necessary. These assessments represent a mechanism of oversight for QA activities used by the Regional Office. Internal and external assessments will be the principal means for determining compliance with and effectiveness of the quality system defined in the Region 6 QMP. Internal assessments of the Region 6 environmental programs are conducted by the QA Staff. External assessments of the Region 6 quality system are conducted by the OMS/EI/OEIP/EQMD. Internal and external assessments should be conducted at a frequency sufficient to ensure that appropriate quality assurance measures are being implemented. The assessments of environmental data operations are generally conducted by contractors, the Regional laboratory, Programmatic Division or Office or are delegated to State, Tribal and local government authorities. The assessments of these entities are accomplished if essential funding for travel is available. If resources are limited, environmental data collection programs or activities that are highly visible will be given priority.

The OMS/EI/OEIP/EQMD has defined in EPA Quality Manual for Environmental Programs CIO 2105-P-01-0 seven types of tools that are used in assessing the quality of an organization's programs:

- MSRs or QSAs,
- surveillance,
- audits,
- **performance evaluations** (PE) or **proficiency testings** (PT),
- peer reviews and technical reviews,
- readiness reviews, and
- data quality assessments and other types of data quality reviews.

These assessments should be performed in accordance with EPA requirements and Agency-wide Quality System documents or Programmatic Division or Office guidance.

The RQAM or Programmatic Division or Office will review plans for assessments or use of assessment tools in the Regional offices or laboratory. The purpose of this review is to ensure that personnel conducting the assessments are adequately trained and have experience in doing the work being assessed. Also, the RQAM or delegated will ensure that personnel conducting the assessments have no direct involvement in the work being assessed and have no real or perceived conflicts of interest. All personnel involved with these assessments shall conduct themselves so as to provide independent and objective reviews of the programs being assessed. Any personnel not meeting these requirements will be replaced on the assessment teams.

The RQAM or delegated will also ensure that personnel conducting assessments have sufficient authority to access to managers and staff of the programs being assessed. This authority will include access to all necessary documents and records. The RQAM will also ensure that these personnel have the necessary permissions or clearances to access restricted information needed in the assessment.

Disputes can occur during assessments and associated responses. When these disputes arise, the dispute resolution process as defined in Section 2.9 of this QMP shall apply.

9.1 MSR or QSA

An MSR or QSA is an independent assessment of management, the management process and structure established by a group to carry out QA responsibilities (the EPA's MSR and QSA processes are defined in Guidance on Assessing Quality Systems EPA QA/G-3). The MSR or QSA includes: review of the adequacy, use and effectiveness of guidance provided by Headquarters to the Regions as well as guidance provided to the States, Tribal Grantees, municipalities, and contractors; the process for preparing important QA documentation; relationship among participants in the program activity under review; the knowledge base of the Regional, State, Tribal, or local government and contractor staff about QA/QC processes and responsibilities; QA process implementation by States, Tribal Grantees, municipalities and contractors; and Regional and State oversight of QA activities, etc.

Specific QA elements addressed in an MSR or QSA include, for example:

- Assessment of the effectiveness of the Quality System or **Quality Management**;
- Procedures for developing DQOs and assessing the results (Data Quality Assessments);
- Procedures for developing and approving QAPPs and the quality of existing QAPP guidance;
- Procedures for developing and approving QMPs;
- Procedures and schedules for conducting audits;
- Tracking system for assuring that the QA program is operating and that corrective actions disclosed by audits have been taken;
- Providing a definite level of financial resources and personnel devoted to implementing the QA program;
- The degree of management support;
- Responsibilities and authorities of the various line managers and the QA Staff for carrying out the QA program; and
- Use of Quality Indicators to monitor Quality Improvement.

Typically, an Assessment Team will be comprised of a Team Leader and one or more members from the QA Staff. The team may be augmented from time to time with members drawn from

a variety of possible sources, such as Programmatic Divisions, Headquarters, other Regional Offices, State offices, Tribal organizations and ORD Laboratories. Selection and composition will depend upon the domain and scope of the assessment. However, each team member will be fully qualified in the area he/she is to assess. If a contractor is part of any of the assessment activities as discussed in the QMP, then any review and assessment of the contractor or the contractor's work products will be conducted in coordination with the agency's CO and any COR.

The schedule for conducting MSRs or QSAs will be developed with the concurrence of the manager whose program is to be reviewed and is then included in the annual QA work plan. If necessary, MSRs or QSAs can be conducted on an unannounced basis. The RQAM is to schedule MSRs or QSAs so that each Division or Program will be reviewed at least every 5 years. More frequent reviews and follow-up reviews will be conducted if findings were significant or corrective actions were ineffective.

Members of an MSR or QSA Team will be selected by the RQAM, or delegated, from the QA Staff members, other Region 6 programmatic staff and state/tribal staff. All members of an MSR or QSA Team shall have completed the Quality Systems Assessment Workshop course conducted by either OMS/EI/OEIP/EQMD or the Region 6 QA Staff.

The Team Leader shall discuss the initial impressions and all preliminary findings from the MSR or QSA with the reviewed managers. This briefing will allow for closure of the objectives set forth in the entrance briefing. Following the MSR or QSA, the Team Leader, in conjunction with Team Members, will prepare a written report, which will be submitted, to the reviewed manager through the appropriate Division Directors. The reviewed manager will prepare a written statement of corrective actions to each of the findings and will return this response to the RQAM within the time specified in the findings report.

Upon receipt of response, the MSR or QSA Team Leader will evaluate corrective actions for adequacy and for timeliness of implementation. If deemed inadequate, the RQAM will be notified to initiate appropriate action.

9.2 Routine Surveillance and Assessment Process of Funding Recommendations

The primary assessment activity performed by the RQAM and Project Officers is the continual **surveillance** of the Regional, Divisional and external Quality Systems as a routine part of review of financial award documents. Each action initiated to transfer funds to a recipient is reviewed to assure the integrity of the internal and external organization's Quality System.

The process of reviewing all grants, cooperative agreements or interagency agreements in the IGMS requires the Project Officer to initiate and attach a locally developed QA Certification form (copy at Appendix C) to each of the FR documents. This QA Certification notes the approval status of the prospective recipient's QMP and approval status of the applicable

existing QAPP(s). If the approval period of the QMP or QAPP is expired, the Project Officer and RQAM are to disapprove the FR thus halting the possible award of funds. In the event the QMP or QAPP has less than 30 calendar days remaining before expiration and no updated document has been received, the FR shall be disapproved. If a revised document has been received and is still under review, the FR may be approved at the discretion of the Project Officer and RQAM.

If a QAPP or QAPPs will be deliverables under the grant or cooperative agreement funding, a QAPP Deliverable QTRAK number will be requested by the Project Officer and included in the appropriate place on the QA Certification form. In the event a Region 6 organizational element has an electronic tracking system for deliverables that includes QAPPs, the requirement to obtain QTRAK numbers for QAPP Deliverables is waived by approval of the RQAM or delegated. This is done to assure the effectiveness of a recipient's QA System.

The FR contains the questions a Project Officer shall respond to regarding a grantee's QA documentation status, applicable requirements, and whether or not Geospatial Information is part of the grant. This also assures that the various programmatic areas of the Regional Office have effective QA Systems. The Programmatic Division or Office reviews and submits the FR, with final approval by the RQAM, assuring that particular elements of the Regional QA System are in place.

9.3 Audits

Internal and external audits are the means for determining compliance with and effectiveness of the quality system and the Region 6 states, tribes and other external organizations defined in the Region 6 QMP. Internal audits of the Region 6 environmental programs are conducted by the QA Staff. External audits of the Region 6 environmental programs are conducted by the Programmatic Divisions, Offices or contractors. Internal audits of the Regional Laboratory are subject to the requirements of the R6 Lab QA Manual, current version. External audits of the Regional Laboratory are performed to verify the International Organizations for Standardization (ISO) 17025 standards by an ISO Accrediting Body. The assessments are performed to maintain ISO accreditation. Internal audits related to field activities are subject to the QAFAP and the Field Operations Management System. The audits are conducted per the Region 6 SOP for Internal Audits and Corrective Actions (R6PROC-009), current version. Internal and external audits may include the participation of the RQAM.

A TSA focuses on the given system for environmental data operations and its associated QA/QC system. TSAs are thorough, systematic and qualitative audits of the measurement system used in environmental data operations. The primary purpose is to assess the adequacy of sampling, measurement, analysis, **calibration** and similar procedures used to generate the data. TSAs that deal with sampling and measurements are field TSAs.

Field TSAs are conducted by the Programmatic Divisions or Offices. TSAs will be planned and conducted in accordance with applicable EPA or Programmatic Division or Office guidance and/or requirements. This includes the Guidance on Technical Audits and Related Assessments for Environmental Data Operations (QA/G-7).

9.4. Laboratory Performance Evaluations or Proficiency Testing

The R6 Lab QA Manual addresses Laboratory PEs or PTs for the Region.

9.5 Peer and Technical Reviews

Peer review refers to the use of independent technical experts who are not associated with the generation of an Agency product critically evaluating the technical aspect of that product. The output of the peer review process is an independent, objective judgment on the technical merit of the product. Peer review can and should encompass a broad range of issues including, but not limited to, statistical design, data collection, monitoring, research and development, data analysis, risk assessment, technical and regulatory support documents, economic analysis, and **remediation** options. The Region 6 peer review coordinator is the Regional Science Liaison located within the immediate office of the Laboratory Services and Applied Science Division. The EPA Peer Review Handbook 4th edition October 2015 provides a roadmap to peer review at EPA and guidance on peer and **technical reviews.**

9.6 Readiness Reviews

Readiness reviews are conducted before specific technical activities (i.e., sample collection, field work and laboratory analysis) are initiated to assess whether procedures, personnel, equipment and facilities are ready for environmental data to be collected according to the QAPP. Conducting **readiness reviews** is the responsibility of the program office administering the work to ensure that an approved QAPP and an approved QMP are in place. Oversight will be done by RQAM during MSRs or QSAs.

9.7 Data Quality Reviews

An important part of data collection efforts is the subsequent review of the data to determine if the data are usable for their intended purpose. The intended use of the data is determined by the project manager through a systematic planning process, such as the DQO process (section 2.2). The project manager will determine the type, quantity and quality of data needed for the project, then determine the necessary review steps for that data. These review processes are to be described in the QAPPs or equivalent project planning documents.

The Superfund and Emergency Management Division relies on the Regional Laboratory to review and validate data generated both in house and by the CLP. The Regional Laboratory

routinely reviews and validates data generated both in house and by contracted laboratories. Those processes are defined in the R6 Lab QA Manual. Other Regional staff, contractors, and grantees may also conduct **data review** activities. These functions are guided by general SOPs and programmatic policies which are designed to permit structured and consistent data review. If a grantee or contractor should need to procure a laboratory to analyze samples, the grantee or contractor will review and validate the analytical data according to EPA requirements as stipulated in the QAPP.

All Regional data collection efforts, internal or external, will require that a portion of the resources be committed to performing data reviews, including **data verification**, data validation, and **data usability assessments**/reviews. A Data Quality Assessment (DQA) is the scientific and statistical evaluation of data to determine if data obtained from environmental data operations are of the right type, quality and quantity support the intended use. EPA's guidance documents Data Quality Assessment: A Reviewer's Guide and Statistical Methods for Practitioners (QA/G-9R and QA/G-9S) may be used to conduct the DQA.

10. QUALITY IMPROVEMENT

10.1 QA Staff Responsibilities

The process of continuous quality improvement leads to the development of a better and more responsive quality system. Toward that end, the QA Staff will perform the following:

10.1.1 RQAM or delegated is responsible for monitoring the QTRAK system for tracking the current status of QMPs and QAPPs.

10.1.2 RQAM will conduct MSRs or QSAs (see Section 9.1) that will require written comments to the findings and where findings were significant and take appropriate follow-up action.

10.1.3 QA Staff will conduct training in the area of the preparation and the review of QAPPs and QMPs and in topics related to QA (See Section 3).

10.1.4 RQAM will hold periodic meetings, at least annually, with divisional program offices on QA related matters of interest.

10.1.5 RQAM represents Region 6 on Agency, Interagency and National QA Policy issues.

10.1.6 RQAM develops and provides EPA QA training for external customers outside of the Region 6 Office when resources are available.

10.1.7 QA Staff will participate in monthly conference calls with the OMS/EI/OEIP/EQMD, other Headquarters staff, and/or the staffs from the other Regions, when conducted as scheduled.

10.1.8 QA Staff and Programmatic Divisions and Offices will maintain a close liaison with the various State/Tribal/Municipal QA officers and laboratory staffs.

10.1.9 Programmatic Divisions and Offices may provide technical assistance to the regulated community.

10.2 QA Forum Responsibilities

To effectively maintain customer alignment of the QA process in Region 6, an advisory group, known as the QA Forum, has been established to accomplish the following tasks:

10.2.1 Solicit feedback from customers to continually improve the QA process in Region 6;

10.2.2 Identify areas of the Region 6 QMP that need improvement or revision; and

10.2.3 Provide feedback to the QA Staff on all aspects of the QA Program.

The QA Forum will meet as needed and provide feedback, in the form of recommendations or findings. The Laboratory Services and Applied Science Division will be the lead in scheduling the QA Forum meetings and in taking and publishing of meeting minutes. During the initial meeting, the QA Forum will establish or re-affirm their internal operating rules for that and following meetings. One additional QA Forum member will be delegated as the Regional IQG Coordinator, regardless of his/her divisional location.

10.3 QA Forum Membership

The Region 6 QA Forum will be an interdivisional organization with one member from each of the following Divisions or Offices and the Regional IQG Coordinator:

- Office of Communities, Tribes and Environmental Assessment,
- Air and Radiation Division,
- Mission Support Division,
- Enforcement and Compliance Assurance Division,
- Land, Chemical and Redevelopment Division,
- Office of Regional Counsel,
- Superfund and Emergency Management Division and
- Water Division.

Members should be either supervisors, senior technical staff or senior staff appointed by the respective Division Director. Members serve at the discretion of the respective Division or Office Director (as applicable). The Laboratory Services and Applied Science Division provides the QA Group members to the QA Forum. The member from the Office of Regional Counsel has the option to attend meetings regularly, or attend meetings where reasonable advance notice has been provided that support on legal matters will be needed.

The RQAM, who serves as the technical advisor to the QA Forum, is responsible for notification to respective Division Directors of a need for a QA Forum member from that Division. Regular meetings of the QA Forum will occur as determined by RQAM.

Appendix A - Terms and Definitions

Accuracy - the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.

Examples of QC measures for accuracy include proficiency testing samples, matrix spikes, laboratory control samples (LCSs), and equipment blanks.[6]

Activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.[2]

Approved - the documented determination that the proposed quality document is suitable for the intended purpose and meets the requirements specified in the applicable Quality Standard.[5]

Assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management review, peer review, inspection, or surveillance.[5]

Audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.[1]

Calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.[1]

Certification - the process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.[6]

Characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.[6]

Comparability - the degree to which different methods or data agree or can be represented as similar. Comparability describes the confidence that two data sets can contribute to a common analysis and interpolation. [6]

Completeness - a measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under correct, normal conditions.[6]

Conformance - an affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting

the requirements. [6]

Data - a collection of facts and estimates from which conclusions may be drawn. [3]

Data Quality Assessment - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use. [6]

Data Quality Objectives (DQOs) - qualitative and quantitative statements derived from the DQO process that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. [1]

Data Quality Objectives (DQO) Process - a systematic planning tool to facilitate the planning of environmental data collection activities. Data quality objectives are the qualitative and quantitative outputs from the DQO Process. See Systematic planning process. [1]

Data Review - the process of examining and/or evaluating data to varying levels of detail and specificity by a variety of personnel who have different responsibilities within the data management process. It includes verification, validation, and usability assessment. [6]

Data Standard - documented consensus-based agreement on the format and definition of common data. [3]

Data Validation - see Validation (Information)

Data Verification - see Verification (Information)

Decision-Maker - project manager, stakeholder, regulator, etc., who has specific interests in the outcome of site-related activities and will use the collected data to make decisions regarding the ultimate disposition of the site or whether to proceed to the next study phase. [6]

Design - specifications, drawings, design criteria, and performance requirements. Also, the result of deliberate planning, analysis, mathematical manipulations and design. [1]

Dissemination - the process of distributing information to the public that represents an official EPA endorsed opinion or decision. (Examples of information not considered a dissemination are information intended only for government employees; EPA responses to requests for Agency records under the Freedom of Information Act [FOIA], the Privacy Act, The Federal Advisory Committee Act [FACA] or other similar laws; correspondence directed to individuals or persons; ephemeral information; and distribution of information in documents filed in or prepared

specifically for a judicial case or an administrative adjudication.) (Source: Section 5.3 & 5.4, EPA Information Quality Guidelines) [5]

Document - recorded information regardless of physical form or characteristics including individual records or items of non-record materials. [5]

Environmental Data - any data or information pertaining to the environment that describe measured outputs from processes; environmental conditions in a specific location; ecological effects and consequences; health effects and consequences; biological, chemical, and radiological conditions; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases, information systems, literature, or the Internet. [5]

Environmental Data Operations - the work performed to collect, produce, use, or report environmental data. [5]

Environmental Measurement – is any data collection activity involving the assessment of chemical, physical, or biological factors in the environment which affect human health. Learn more about these programs and tools that aid in environmental decisions.

Environmental Programs - the activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples. [5]

Equivalent Document - a set of documents that contains all the information and management controls (signatures) as the required documents used in the Standard. [5]

Finding - an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative and is normally accompanied by specific examples of the observed condition. [6]

Financial Assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements. [1]

Graded Approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results. [1]

Guidance - a non-mandatory compilation of advice, examples, best practices, or past experience. Guidance may supplement procedures. [1]

Historical Data - see secondary data.

Independence - the lack of a causal relationship between things, regardless of their statistical correlation; freedom from bias and external influences that could affect objectivity. [3]

Information - for purposes of this policy, information means any communication or representation of knowledge such as facts or data, in any medium or form, including, but not limited to, textual, numerical, graphic, cartographic, narrative, or audiovisual forms. (OMB Information Quality Guidelines). [3]

Information Dissemination - see Dissemination

Information Integrity - see Integrity

Information Quality Guidelines (IQG) - an Agency document that defines a basic standard of quality (including objectivity, utility, and integrity) for information products disseminated by EPA. For influential information products, the basic standard of quality also includes reproducibility and transparency. [5]

Information System - an organized collection, storage, and presentation system of data for decision making, progress reporting, and for planning and evaluation of programs. It can be either manual or computerized, or a combination of both. [3]

Information Technology - the study, design, development, implementation, support, or management of computer-based information systems, particularly software applications and computer hardware. [5]

Inspection - the examination or measurement of an item or activity to verify conformance to specific requirements. [6]

Integrity (information) - assurance that the information is protected from unauthorized access or change and in not compromised through corruption or falsification. [5]

Item - an all-inclusive term used in place of the following: appurtenance, facility, sample assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data. [2]

Management - those individuals directly responsible and accountable for planning, implementing, and assessing work. [1]

Management System Review (MSR) - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. [1]

Method - a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be

executed. [1]

Organization - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration. In the context of this Standard, an EPA organization may be an Office, Region, National Research Center or Laboratory, or a sub-unit such as a division, branch, section, or team. [5]

Peer Review - a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. [1]

Performance Evaluation (PE) - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory. [2]

Policy - a high-level statement about an Agency requirement designed to influence and determine decisions, actions, and other matters. It is usually driven by statute, executive order, the mandate of an oversight agency or Congress, or the head of the organization. [5]

Precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed generally in terms of the standard deviation. [1]

Product - the intended result or final output of an activity or process that is disseminated or distributed among EPA organizations or outside of EPA. [3]

Procedure - the required steps, course of action, or processes needed to accomplish or satisfy a policy. [5]

Process - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation. [3]

Proficiency testing (PT) sample - a sample, the composition of which is unknown to the laboratory or analyst, which is provided to that laboratory or analyst to assess capability to produce results within acceptable criteria. PT samples can fall into three categories: (1) prequalification, conducted prior to a laboratory beginning project work, to establish initial proficiency; (2) periodic (e.g., quarterly, monthly, or episodic), to establish ongoing laboratory proficiency; and (3) batch specific, which is conducted simultaneously with analysis of a sample batch. A PT sample is sometimes called a performance evaluation sample. [6]

Project - an organized set of activities within a program. [6]

QTRAK - a Region 6 Computer Program that contains database information on Quality Management Plans and Quality Assurance Project Plans. This computer program is available to Region 6 EPA Program Managers, Project Officers, and the QA Staff for planning, tracking and assessment of the status of Regional Quality Management Plans and the associated Project Plans.

Quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user. [1]

Quality Assurance (QA) - a management or oversight function that deals with setting policy and running an administrative system of management controls that cover planning, implementation, review and maintenance to ensure products and services are meeting their intended use. [3]

Quality Assurance (QA) Coordinator - the individual responsible for overseeing the quality systems of the Laboratory. This oversight includes formulation, recommendations to lab management and implementation of QA policy. In assessment roles the QA Coordinator monitoring participation and performance on EPA laboratory performance evaluation studies, performing quality system assessments, and organizing review and update of SOPs, and the QA Manual.

Quality Assurance (QA) Forum - the interdivisional organization, with an advisory function for Quality Assurance activities of Region 6 in general and the Quality Assurance Staff specifically. Acts as a liaison between the Programmatic Divisions or Offices and the QA Group.

Quality Assurance Manager (QAM) - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.[1]

Quality Assurance (QA) Manual – a document that establishes the policy and program requirements for the conduct of all environmentally related measurements performed by or for the Laboratory. The primary purpose of the document is to establish and maintain uniform operational and quality control guidance for regional analytical chemistry activities and QA, QC activities.

Quality Assurance Project Plan (QAPP) - a document describing in comprehensive detail the necessary QA, QC, and other technical activities that shall be implemented to ensure that the results of the work performed will satisfy the stated performance objectives and criteria. [5]

Quality Assurance (QA) Staff - the QA Group (Regional Quality Assurance Manager, Regional Field Quality Manager, QA Coordinator, Regional QA Officers and QTRAK Administrator) in the Laboratory Services and Applied Science Division and subject matter experts/technical

reviewers in the Programmatic Divisions, Offices or programs. The QA Group reports to the Deputy Division Director for Laboratory Services and Applied Science.

Quality Control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet

the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality. [3]

Quality Improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation. [1]

Quality Management - that aspect of an organization's overall quality management system that drive the implementation of EPA's Quality Policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to an organization's quality program. [3]

Quality Management Plan (QMP) - a formal document or manual that describes a quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted. [3]

Quality System - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities. [4]

Readiness Review - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work. [1]

Record (quality) - a document that furnishes objective evidence of the quality of products, services, or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media. [6]

Regional Field Quality Manager - the individual responsible for ensuring QAFAP implementation and assessing the field activities quality system procedures within Region 6.

Regional Quality Assurance Manager (RQAM) - the individual designated as the principal manager within Region 6 having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the

Region (see QAM definition). NOTE: Personnel having QA or QC duties may be referred to as QA Staff.

Remediation - the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health. [2]

Representativeness - a measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition. [6]

Requirement - an expression of the content of a Standard conveying a criterion to be fulfilled if compliance is to be claimed and from which no deviation is permitted. [5]

Secondary Data - data not originally collected for the purpose for which they are now being used. In addition, the level of QA/QC provided at the time of the original data collection may be unknown. (See also existing data, historical data.) [6]

Shall - when used in a sentence, a term denoting a requirement that has to be met. [6]

Standard - an accepted, consensus-based specification which defines systems, processes, methodologies, or practices. It provides a basis for assuring consistent and acceptable minimum levels of quality, performance, safety, and reliability. Standards usually are included in or accompany procedures. [5]

Standard Operating Procedure (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks. [1]

Subject Matter Expert (SME)- is an individual(s) with specific expertise and responsibility in a particular topic, area or field (online information) or a person with bona fide expert knowledge of the responsibilities, duties, day-to-day functions, competencies and requirements of a position. (Delegated Examining Operations Handbook: A Guide for Federal Agency Examining Offices)

Supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant. [1]

Surveillance (Quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled. [1]

Systematic planning process - Systematic planning is a process that is based on the scientific method and includes concepts such as objectivity of approach and acceptability of results.

Systematic planning is based on a common sense, graded approach to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the

available resources. This framework promotes communication among all organizations and individuals involved in an environmental program. Through a systematic planning process, a team can develop acceptance or performance criteria for the quality of the data collected and for the quality of the decision. [6]

Technical Review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied. [1]

Technical Systems Audit (TSA) - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system. [1]

Traceability - The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. [6]

Usability Assessment - the evaluation of data based upon the results of data validation and verification for the decision(s) being made. Reviewers assess whether the process execution and resulting data meet quality objectives based on the criteria given in the QAPP. [5]

Validation (Information) - the confirmation by examination and provision of objective evidence that the particular requirement for which the information is intended are fulfilled; the process of determining whether the specifications were appropriate and that the verified results will meet the data user's needs. [5]

Verification (Information) - the confirmation by examination and provision of objective evidence that validated information fulfills specified requirements; the process of checking whether the information met the project's specifications. [5]

Work - the process of performing a defined task or activity. [2]

Source of definitions:

1. EPA Quality Manual for Environmental Programs, CIO 2105-P-01-0, May 5, 2000.
2. American National Standard, Quality Management Systems for Environmental Information and Technology Programs (E-Standard), ANSI/ASQ E4- 2014.
3. EPA Quality Policy, CIO 2106.0, October 20, 2008.
4. EPA Order, Policy and Program Requirements for The Mandatory Agency-Wide Quality System, CIO

2105.0, May 5, 2000.

5. Quality Standard for Environmental Data Collection, Production and Use by EPA Organizations, CIO 2106-S-01 (Draft Final, 2/22/12).
6. Uniform Federal Policy for Quality Assurance Project Plans (UFP QAPP Manual), March 2005.

Appendix B - Quality Assurance Memorandum of Understanding

Quality Assurance Memorandum of Understanding

Between The

Region 6 Management Division (6MD)

And The

Region 6 Water Division (6WQ)
Region 6 Multimedia Division (6MM)
Region 6 Superfund Division (6SF)
Region 6 Compliance Assurance & Enforcement Division (6EN)
Office of External Affairs (6XA)
Office of Regional Counsel (6RC)
Office of Environmental Justice, International and Tribal Affairs (6RA-DA)

I. Introduction

It is both a Regulatory requirement and policy of EPA that all environmental programs conducted by or on behalf of EPA shall establish and implement effective Quality Systems. EPA Order CIO 2105.0, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" establishes policy and program requirements for the preparation and implementation of organizational or programmatic management systems pertaining to quality and contains the minimum requirements for the mandatory agency-wide quality system. Specifically, this Order states;

(1) It is EPA policy that all environmental programs performed by EPA or directly for EPA through EPA-funded extramural agreements shall be supported by individual quality systems that comply fully with the Quality systems for environmental data and technology programs, American National Standard ANSI/ASQ E4- 2014; and

(2) Regional Administrators and senior managers shall:

(a) Ensure that all Regional components and programs comply fully with the requirements of this Order.

(b) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the organization's approved QMP.

(c) Ensure that all environmental programs implemented through extramural agreements comply fully with applicable QA and QC requirements.

(d) Ensure that the environmental data from environmental programs delegated to State, local, and Tribal governments are of sufficient quantity and adequate quality for their intended use and are used consistently with such intentions.

(e) Ensure that training is available for State, local, and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA and QC activities that they may be expected by EPA to perform.

(f) Perform periodic assessments of Regional organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.

(g) Ensure that deficiencies highlighted in the assessments are appropriately addressed.

(h) Identify QA and QC training needs for all levels of management and staff and provide for this training.

The undersigned enter into this Memorandum of Understanding (MOU) to ensure that Regional resources are used effectively to achieve compliance with the QA/QC requirements imposed by EPA Order CIO 2105.0. This MOU documents the respective Divisional and Office relationships for implementing an effective quality system that meets or exceeds Agency and National Standard requirements.

II. Roles and Responsibilities

Region 6 utilizes a decentralized QA organization. Under the Delegation of Authority outlined in the Region's QMP, the Management Division is the focal point in the Region for Quality Systems policy. The Management Division, in conjunction with the Region's QA Forum, is responsible for developing QA/QC requirements and for overseeing the over-all implementation of the Agency-wide Quality System within the Region. The Assistant Regional Administrator for Management (ARA) is designated as the Region's Senior Management Official for Quality. The Regional Quality Assurance Manager (RQAM) is designated to serve as the central management authority for this program. The RQAM is located in the Management Division and individual Division QA Officers (DQAOs) are located in the Water Quality Division, Compliance Assurance and Enforcement Division, Superfund Division, and the Multimedia Division (hereinafter referred to as the Program Divisions in this MOU). The RQAM in the Management Division shall support the QA needs of the Office of External Affairs, the Office of Environmental Justice, Tribal and International Affairs and the Office of Regional Counsel (hereinafter referred to as supported offices). The Management Division, Environmental

Services Branch in Houston has a Quality Assurance Coordinator that reports to the Chief of the Environmental Services Branch. The organizational location of the RQAM, each DQAO and the ESB QA Coordinator shall be such as to satisfy the independence and organizational reporting requirements contained in paragraph 6.a.(1) of EPA Order CIO 2105.0. The Divisional QAOs will receive QA work assignments related to regional QA activities from their respective program office supervisor. A description of the Region's over-all quality system, as well as delegation of QA responsibilities to individual Divisions is contained in the Region 6 QMP. Specifically, section 1.13 addresses the functions/responsibilities of the RQAM; section 2.1 addresses the functions/responsibilities of the DQAOs; and section 10.2 addresses the functions/responsibilities of the Region's QA Forum. Each Divisional QMP describes their individual quality system and specifically details the roles and responsibilities of staff members (DQAO, Project Officers, Project Managers, Task Order Managers, Work Assignment Managers, Remedial Program Managers, On Scene Coordinators, Contracting Officer Representatives, etc.) to assure implementation of its QA System.

To ensure that the Region fully complies with the Agency's mandatory Quality System requirements the Management Division, Program Divisions and the supported offices mutually agree to the following commitments to accomplish specific components of the Region's quality system:

QA Forum

Section 10.2 of the Region's QMP details the roles and responsibilities of the Region's QA Forum. Each Division has two members, and each supported office has one member. One member is the Divisional QAO (and the ESB QA Coordinator) and the other member should be either a supervisor or senior technical staff member who is appointed by and serves at the discretion of their Division or Office Director. The Forum meets as needed. The Management Division agrees to be lead in scheduling the QA Forum meetings and in the taking and publishing of meeting minutes. The Program Divisions agree to support the Forum through their members and to exercise their role in appointing, reappointing, extending or removing their "at large" members as outlined in section 10.2 of the Regional QMP. During the initial meeting of the QA Forum will establish or re-affirm their internal operating rules for that and following meetings. One additional QA Forum member will be the individual designated as the Region's Information Quality Guidelines Officer, regardless of his/her divisional location. Office of Regional Counsel agrees to provide legal support to the QA Forum at meetings where reasonable advance notice has been provided if such support is needed, or can designate an individual to attend meetings regularly.

Quality Assurance Annual Report and Work Plan (QAARWP)

Chapter 4 of the Agency's Quality Manual, CIO 2105-P-01-0, requires that each Agency organization prepare a QAARWP to report progress made during the previous fiscal year in the implementation of its quality system and quality functions planned for the upcoming fiscal year. The call letter for the QAARWP usually is issued in mid-September with submission required (under the Regional Administrator's signature) by the end of October. The Management Division will be the lead in preparing the QAARWP and the Program Divisions and each supported office agree to provide input to the plan through their QA Forum members to the Management Division in a timely manner. Prior to final submission of the QAARWP to the RA for signature, the proposed QAARWP will be submitted to the QA Forum and individual Division Directors for concurrence.

Revision of the Region 6 QMP

Paragraph 3.2.4 of the "EPA Quality Assurance Manual for Environmental Programs CIO 2105-P-01-0" contains the criteria for when the Region's over-all QMP must be revised/updated. The Management Division, through the RQAM, agrees to take the lead in accomplishing these revisions. The Program Divisions and each supported office agree to support the accomplishment of these revisions through their QA Forum members. Any revision will be processed through the QA Forum and each Division Director for concurrence prior to being submitted to the RA for approval.

Revision of Divisional QMPs

Periodically, a Division's QMP will require revision and in accordance with the Regional QMP, the RQAM is required to review and approve each Divisional QMP. The Program Divisions agree to submit their revised QMPs to the RQAM within 90 calendar days after notification of approval, by Headquarters, of the Regional QMP. When a Program Divisions' revised QMP is submitted to the RQAM, the review will be accomplished within the time frame allowed in the Region's QMP. The Management Division's QMP will address the QA policies and processes of the supported offices and will be revised with assistance from each supported office.

Management System Reviews and Quality System Assessments

One of the tools used by the Agency to determine if the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained is the Management System Review (MSR) or Quality System Assessment (QSA). The Management Division and the program office will be responsible for conducting both internal MSRs or QSAs (of each Program Division and each supported office) and external MSRs or QSAs of State, local, and Tribal organizations that receive financial assistance from the Region. Paragraph 9.1 of the Regional QMP outlines the

procedures for conducting MSRs or QSAs as well as the frequency of the reviews. The Management Division with the participation of the program office will schedule, coordinate all activities, assure that the results are reported, and assure that corrective measures (if required) are completed for each MSR. The Program Divisions and each supported office agree to provide qualified MSR or QSA team members (if requested) for internal or external MSRs or QSAs (each team member must have completed the QA training requirements contained in the Regional QMP).

Technical System Audits

Technical System Audits (TSAs) focus on the given system for environmental data operations. The primary purpose is to assess the adequacy of sampling, measurement, analysis, calibration, and similar procedures used to generate data. TSAs that deal with sampling and measurements are field TSAs. Those that deal with a laboratory's operation, capabilities, and the reliability of data produced are laboratory TSAs. At the request of a Program Division, the Management Division, Environmental Services Branch, will schedule and conduct a laboratory TSA, however, audit team members may be requested from a Program Division. Paragraph 9.3 of the Regional QMP delegates the responsibility for conducting field TSAs to the Program Divisions, and the discussion of how field TSAs are planned, implemented, reported, and the accomplishment of corrective action is contained in the individual Divisional QMPs. The RQAM will determine the adequacy of field TSAs when Divisional QMPs are reviewed, and during MSRs and other audits. All parties agree that a Divisional QAO may seek assistance in conducting a field TSA from the RQAM, other Divisional QAOs, or the Regional Laboratory.

Quality Assurance Training

The EPA Order for QA requires the RA to ensure that QA training is provided to Regional Staff as well as for State, local, and Tribal governments performing environmental programs for the Region. The Management Division, with assistance of the Program Divisions, will coordinate and schedule QA training, arrange for facilities, publish training notices, enroll students, and issue training certificates. The Program Divisions agree to provide the services of their respective DQAO as an instructor for QA courses that the DQAO has been previously qualified to teach. If the QA training involves travel funds to accomplish the training the Program Division will fund the travel of their respective DQAO or acceptable alternate from another Division.

Review of QMPs submitted by Financial Assistance Recipients

QMPs submitted to the Region are required to be submitted to the RQAM. Once received, the RQAM will issue a QTRAK number for the QMP, determine which DQAO should be lead for the review and route it to that DQAO. If the QMP is not media specific (i.e., a multimedia or multi programmatic), the RQAM will coordinate with the respective DQAOs and their supervisors to

determine workload before assignment for review. In accordance with the Regional QMP, the RQAM or designee is the final approval authority for QMPs. Each Program Division agrees that (1) its DQAO will perform the review of assigned QMPs within the time frames outlined in the Regional QMP, (2) the DQAO will provide constructive comments if recommending disapproval, and (3) the DQAO will sign the QMP indicating concurrence or otherwise indicate their concurrence if the recommendation is for approval.

Quality Assurance Tracking System (QTRAK)

QTRAK is a computer program that contains database information on QMPs and Quality Assurance Project Plans (QAPPs) for the program managers, project officers, the RQAM and the DQAOs. The Management Division agrees to continue to maintain and upgrade this system and to provide training to the Regional staff as necessary.

Professional Development for Regional QA Personnel

It is imperative that all QA personnel continue to be informed of changes in the Agency's Quality System and/or policies and of developments or changes in National, International or Industry Standards.

QA Outreach to the Regulated Community

In an attempt to keep the QA staffs in the regulated community informed of new requirements or changes in the Agency's QA Program, the Region has, for a number of years, sponsored an annual State/EPA QA Conference in Dallas. The entire QA Staff will take the lead in scheduling and coordinating this conference, if resources allow. Each Program Division agrees to allot time for its DQAO and QA Forum member(s) to assist in planning and assisting with this conference and to provide speakers on an as requested basis.

Travel Funding

This MOU contains commitments by the Management Division for travel funds for the RQAM, and the ESB QA Coordinator to conduct essential centralized QA functions such as external MSRs, QA training and QA professional development. Travel funds necessary to accomplish QA functions delegated to Program Divisions and each supported office by the Regional or a Divisional QMP, such as QA training support, MSR team member support are the responsibility of the individual Program Divisions and each supported Office. If the RQAM or any other QA Staff are requested to provide assistance to a Programmatic Division, supported office or their customers, any travel funds involved are the responsibility of the applicable Program Division.

Equity

In order to accomplish the Regional QA Program goals, each Program Division will provide travel funding for the conduct of QA training and to perform MSRs or QSAs. Each Program

Division will provide staff resources for the conduct of QA training and to perform MSRs or QSAs. The RQAM will attempt to assure the burden of QA related travel funds and the use of Programmatic staff are equitable among the Program Divisions for the entire QA Program.

Acting RQAM

Periodically, it may be necessary to designate an acting RQAM to assure that centralized QA functions are accomplished in a timely manner. The Management Division will consult and coordinate with the Program Divisions before designating an acting RQAM outside of the Division.

Acting DQAO

Periodically, it may be necessary to designate an acting DQAO to assure that Program Division QA functions are accomplished in a timely manner. The Program Division will consult and coordinate with the Management Division before designating an acting Divisional QAO.

III. Reopener, Termination and Effective Date

This agreement is meant to provide the framework within which the Divisions intend to operate. This MOU begins (replace with Date of Revised QMP local approval) and continues until such time as a new MOU is signed. Any party may request revisions to the MOU. In the event of revisions, the portion thereof not altered by the revisions shall remain in full effect.

Approvals, Quality Assurance Memorandum of Understanding

Name: James McDonald
Title: Assistant Regional Administrator for Management
Signature: James McDonald Date: 8/31/17

Name: William K. Honker, P.E.
Title: Director Water Division
Signature: for WK Honker Date: 08/24/2017 9/12/17

Name: Wren Stenger
Title: Director Multimedia Division
Signature: _____ Date: 8/31/17

Name: Carl E. Edlund, P.E.
Title: Director Superfund Division
Signature: _____ Date: 8/31/17

Name: Cheryl T. Seager
Title: Director Compliance Assurance and Enforcement Division
Signature: _____ Date: 8/31/2017

Name: David W. Gray
Title: Director Office of External Affairs
Signature: _____ Date: 9/8/17

Name: James Payne, Jr.
Title: Regional Counsel
Signature: _____ Date: 9/6/17

Name: Arturo Blanco
Title: Director Office of Environmental Justice, International and Tribal Affairs
Signature: _____ Date: 8/31/17

Appendix C - Quality Assurance Certification Forms and Competency Policy Checklist

EPA REGION 6 QUALITY ASSURANCE CERTIFICATION FOR ASSISTANCE AGREEMENTS

Grant/IAG/Contract Number	Recipient
Agreement Description	Amount Budgeted & Agreement Period

QA OFFICER'S AND QA MANAGER'S CERTIFICATION

We, the undersigned, certify that (check each applicable element):

( ) the requirements under this extramural agreement do not include any activities that involve the use of environmentally related measurements and related decisions. Therefore, an exemption is granted from EPA Quality Assurance and FEM Competency Policy Requirements.

( ) an approved Quality Management Plan (QMP) compliant with ANSI/ASQC E-4 and/or EPA QA/R-2 currently exists and is on file with the EPA Region 6 Regional Quality Assurance Manager as identified by QTRAK number _____. ***This block requires completion of below certification and assigned QTRAK number for the QA Project Plan/s under the subject extramural agreement.***

( ) this extramural agreement is an Interagency Agreement (IA) and is exempt from the FEM Competency Policy Requirements.

RECOMMENDATION	RQAM APPROVAL
QA Cert. Project Officer	Reg. 6 QA Manager
Printed Name	Printed Name
Mailcode, Ext & Date	Mailcode, Ext & Date

PROJECT OFFICER'S CERTIFICATION

I, the undersigned EPA Project Officer, having completed the EPA Region 6 QA Certification Course requirement and being officially recognized to oversee this/these project/s (check applicable elements):

( ) certify that each approved Quality Assurance Project Plan (QAPP) is compliant with EPA QA/R-5, is on file with the appropriate program office, and is registered with the Regional QA Manager as identified by QTRAK number(s) _____.

( ) certify that the Quality Assurance Project Plan(s) (QAPP) is/are required for completion of the referenced assistance agreement and will be developed and submitted as a deliverable under this award and that no activities will be conducted until the QAPP has been received, reviewed and approved. The following QTRAK number is assigned for tracking purposes _____.

(Continues on next page)

( ) ***In accordance with the Competency Policy, as Project Officer I have determined that the recipient meets the requirements for demonstration of competence through ongoing successful past performance to similar statement(s) of work "for this continuing environmental program."***

( ) Grantee has submitted the *R6 Checklist for the Implementation of the FEM Policy for Competency for Grants and Cooperative Agreements* (attached) in accordance with the FEM Competency Policy, documenting that the recipient meets the requirements for demonstration of competence without past performance for programs other than continuing environmental programs. (New grantees and "first and only" submission for tribes and programs that repeat annually but are not considered CEPs. Ex: National Estuary Program)

( ) Grantee has previously submitted the *R6 Checklist for the Implementation of the FEM Policy for Competency for Grants and Cooperative Agreements* in accordance with the FEM Competency Policy, documenting that the recipient meets the requirements for demonstration of competence through ongoing successful past performance to similar statement(s) of work for programs other than the continuing environmental programs.

( ) It has been determined that at the time of award the total maximum value of the assistance agreement does not nor is it presently expected to exceed $200,000 in federal funding over the life of the agreement. Specific grant competency term and condition is not required.

_____
QA Cert. Project Officer

_____
Printed Name

_____
Mailcode, Ext. & Date

EPA REGION 6 QUALITY ASSURANCE CERTIFICATION
FOR WATER DIVISION (WD) ASSISTANCE AGREEMENTS

Grant/IAG/Contract Number	Recipient
Agreement Description	Amount Budgeted & Agreement Period

QA OFFICER'S AND QA MANAGER'S CERTIFICATION

We, the undersigned, certify that (check each applicable element):

( ) the requirements under this extramural agreement do not include any activities that involve the use of environmentally related measurements and related decisions. Therefore, an exemption is granted from EPA Quality Assurance and FEM Competency Policy Requirements.

( ) an approved Quality Management Plan (QMP) compliant with ANSI/ASQC E-4 and/or EPA QA/R-2 currently exists and is on file with the EPA Region 6 Regional Quality Assurance Manager as identified by QTRAK number _____. ***This block requires completion of below certification and assigned QTRAK number for the QA Project Plan/s under the subject extramural agreement.***

( ) this extramural agreement is an Interagency Agreement (IA) and is exempt from the FEM Competency Policy Requirements.

RECOMMENDATION	RQAM APPROVAL
QA Cert. Project Officer	Reg. 6 QA Manager
Printed Name	Printed Name
Mailcode, Ext & Date	Mailcode, Ext & Date

PROJECT OFFICER'S CERTIFICATION

I, the undersigned EPA Project Officer, having completed the EPA Region 6 QA Certification Course requirement and being officially recognized to oversee this/these project/s (check applicable elements):

( ) certify that each approved Quality Assurance Project Plan (QAPP) is compliant with EPA QA/R-5, is on file with the appropriate program office, and is registered with the Regional QA Manager as identified by QTRAK number(s) _____.

( ) certify that the Quality Assurance Project Plan(s) (QAPP) is/are required for completion of the referenced assistance agreement and will be developed and submitted as a deliverable under this award and that no activities will be conducted until the QAPP has been received, reviewed and approved. QAPPs that are designated as deliverables under this grant will be tracked in BRATs and upon receipt shall be entered into the QTRAK system.

(Continues on next page)

( ) ***In accordance with the Competency Policy, as Project Officer I have determined that the recipient meets the requirements for demonstration of competence through ongoing successful past performance to similar statement(s) of work "for this continuing environmental program."***

( ) Grantee has submitted the *R6 Checklist for the Implementation of the FEM Policy for Competency for Grants and Cooperative Agreements* (attached) in accordance with the FEM Competency Policy, documenting that the recipient meets the requirements for demonstration of competence without past performance for programs other than continuing environmental programs. (New grantees and or grantees who've demonstrated poor past performance)

( ) Grantee has previously submitted the *R6 Checklist for the Implementation of the FEM Policy for Competency for Grants and Cooperative Agreements* in accordance with the FEM Competency Policy, documenting that the recipient meets the requirements for demonstration of competence through ongoing successful past performance to similar statement(s) of work for programs other than the continuing environmental programs.

( ) It has been determined that at the time of award the total maximum value of the assistance agreement does not nor is it presently expected to exceed $200,000 in federal funding over the life of the agreement. Specific grant competency term and condition is not required.

_____
QA Cert. Project Officer

_____
Printed Name

_____
Mailcode, Ext. & Date

R6 CHECKLIST FOR THE IMPLEMENTATION OF THE FEM POLICY FOR COMPETENCY FOR GRANTS AND COOPERATIVE AGREEMENTS

May 2014

This checklist is to be used by the applicant as a guide on the documents that may be considered to address and demonstrate competency. Applicants must have on record justification for each checked box, additionally these documents are required to remain on file. Your records should be preserved for three years from the date of the submission of the final FFR. If any litigation, claim, negotiation, audit, or other action involving the records has been started before expiration of the three-year period, the records must be retained until completion of the action and all issues are resolved. To ensure proper disposition of all your records on this project, please refer to 40 CFR Part 31.42. After the requirements of this regulation are satisfied, you may dispose of these records in accordance with your standard practices.

Please complete Section A (by providing the necessary items if applicable) and/or Section B (by checking the appropriate box), and return to the EPA Project Officer during work-plan negotiation or prior to carrying out any activities involving the generation or use of environmental data under the current or upcoming agreement. One or more of the competency documentations listed on page two can also be included in the organization's Quality Management Plan, Quality Assurance Project Plan and/or Laboratory QA Manual. Additionally, by submitting these items a grantee "warrants, represents, and agrees that it and all its contractors, employees and representatives will comply with all APPLICABLE provisions of 40 CFR Chapter 1, Subchapter B, INCLUDING BUT NOT LIMITED TO the provisions of 40 CFR Parts 31, 32, 34, and 35" as described in EPA Administrative Terms and Conditions.

SECTION A

At a minimum, the following documentation must be provided to U.S. EPA in addition to the completed checklist:

Box	Competency Demonstrations in the Field of Sampling &/or Analyses to be Conducted	Check (√) All That
1.	Current ce1tificate(s) of accreditation/certification for applicable sampling and/or analysis. Usually included in the Laboratory QA Manual or the organization QMP, if available.	

If your organization relies on accreditation/certification to demonstrate its qualifications in the field of sampling or analyses to be conducted (as implied by checking, the above, Box 1), please attach the following minimum documentation as required by the Competency Policy. If this doesn't apply, please proceed to Section B and fill out Boxes 2 through 10.

- A copy of the organization's quality system documentation. It may be called a Quality Management Plan (QMP), a quality manual, or some other name, depending on the organization. It should describe how the organization will plan, implement and assess the effectiveness of its QA/QC operations applied to environmental programs. It should conform to ANSI/ASQ E-4 2004, "Quality Systems for Environmental Data and Technology Programs: Requirements with Guidance for Use," as well as the U.S. EPA Quality documents listed in the answer to FAQ #9 and their referenced guidance. In some cases, analytical laboratories are now following ISO Guide 17025.

- Copies of the dated certificate(s) of accreditation/certification from those accrediting bodies indicating the applicable field(s) of sampling or analysis, and the period for which the accreditation/certification is valid.

- If the accreditation/certification is limited to specific sampling techniques, analytes or laboratory instrumentation, then a complete list of those techniques, analytes or instruments must be provided.

Listed below are other document(s) that may be used to demonstrate competency in addition to QMP/QAPP:

Box	Competency Demonstrations in the Field of Sampling &/or Analyses to be Conducted	Check (√) All That Apply
2.	Results from ongoing participation by the organization in relevant proficiency testing studies, round-robin programs or equivalent. -Applicable to Laboratories	
3.	Documented successful demonstrations of competency with applicable sampling and/or analytical equipment.	
4.	Documented experience with parameters and methods of interest.	
5.	References of past performance (Other similar project grants is acceptable).	
6.	Recent reports of technical and/or quality system assessments/audits of the organization, including associated corrective action plans.	
7.	Documented position descriptions for key personnel detailing major responsibilities and qualifications (e.g., education, training certificates, job experience, and active participation in professional associations. Also discussed in QMP, QAPP and Lab QA Manual).	
8.	Organizational quality documentation, such as a QMP, laboratory QA manuals, field quality manuals that provide descriptions of the organization 's quality policies. Such documents should include: all requirements described in EPA Requirements for Quality Management Plans (EPA QA/R-2) https://www.epa.gov/sites/production/files/2016-06/documents/r2-final.pdf	
9.	Technical/Project Level quality documentation, such as QAPPs, Sampling and Analysis Plans (SAPs) and/or standard operating procedures (SOPs). Such documents should include: auditing practices, descriptions of applicable equipment, method sensitivities, reporting practices, capacity, etc.	
10.	Other -Describe the competency demonstration(s)	

*References

- FEM website: http://www.ega.gov/fem/lab_comp.htm.
- Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements
- Frequently Asked Questions (FAQs) for Agreements
- DRAFT Examples of Competency Demonstration for Recipients
- Catalog of Federal Domestic Assistance (CFDA)

Project Manager Name (Please TYPE)

Project Manager Signature / Date

Region 6 has drafted a list of competency demonstrations that may be used by Continuing Environmental Program (CEP) applicants when preparing a statement demonstrating competency.

Competency Demonstration #1 – Documented successful demonstrations of competency with applicable sampling and/or analytical equipment.

> "Competency is demonstrated through the applicant's experience using (manufacturer name/model) water quality monitoring equipment for (number of years) years.

Competency Demonstration #2 - References of past performance (Other similar project grants is acceptable).

> "Competency is demonstrated through the maintenance of quality assurance project plans for data collection activities for water quality monitoring."

Competency Demonstration #3 - Recent reports of technical and/or quality system assessments/audits of the organization, including associated corrective action plans.

> "Competency is demonstrated by the Region 6 Quality Assurance Management Review conducted on (date)."

Competency Demonstration #4 - Documented position descriptions for key personnel detailing major responsibilities and qualifications (e.g., education, training certificates, job experience, and active participation in professional associations. Also discussed in QMP, QAPP and Lab QA Manual).

> "Competency is demonstrated through QA-QC documents that state position descriptions for key personnel detailing major responsibilities and qualifications."

> "Competency is demonstrated through (type of training) training course taken on (date of training). Certificate is available upon request."

Competency Demonstration #5 - Organizational quality documentation, such as a QMP, laboratory QA manuals, field quality manuals that provide descriptions of the organization's quality policies. Such documents should include: all requirements described in EPA Requirements for Quality Management Plans (EPA QA/R-2) http://www.epa.gov/quality/qs-docs/r2-final.pdf.

> "Competency is demonstrated through the Quality Management Plan that provides descriptions of the quality policies, including all requirements described in EPA QA/R-2."

Competency Demonstration #6 - Technical/Project Level quality documentation, such as QAPPs, Sampling and Analysis Plans (SAPs) and/or standard operating procedures (SOPs). Such documents should include: auditing practices, descriptions of applicable equipment, method sensitivities, reporting practices, capacity, etc.

> "Competency is demonstrated through the EPA approval of the Pueblo/Tribe's Quality Assurance Project Plan for GIS/GPS data collection."